PUBLIC HEALTH PROGRAMS

AIDS

HEARINGS

BEFORE THE

SUBCOMMITTEE ON
HEALTH AND THE ENVIRONMENT

OF THE

COMMITTEE ON
ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIRST CONGRESS

SECOND SESSION

FEBRUARY 26, 1990—TUBERCULOSIS CONTROL PROGRAM REAUTHORIZATION—H.R. 4097
MARCH 7, 1990—CHILDHOOD IMMUNIZATION PROGRAM REAUTHORIZATION

Serial No. 101-134

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PUBLIC HEALTH PROGRAMS

Tuberculosis Control Program Reauthorization

MONDAY, FEBRUARY 26, 1990

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:45 a.m. in room 2322, Rayburn House Office Building, Hon. Henry A. Waxman (chairman) presiding.

Mr. WAXMAN. The meeting of the subcommittee will come to order.

This morning's hearing is H.R. 4097, a bill to provide for the reauthorization of the Tuberculosis Control Program administered by the Centers for Disease Control.

This hearing should not be necessary. We have had the knowledge and the tools to eliminate TB for years. TB should be a 19th century disease and should have been eliminated from modern life.

Instead it has been treated by the administration and the Congress alike as just one more chronic public health problem that can be given rhetorical attention with no serious commitment. We have allowed TB in this country to continue to smolder, rather than eradicating the disease altogether.

Over the past 5 years, we have seen the unforgiving results of such shortsightedness. After 20 years of decline, in 1986 the number of TB cases increased in this country, and from that year on progress against the disease has been thwarted.

These are complicated statistics. They include outbreaks among young children, in nursing homes, among refugees, among people with AIDS, and among the homeless.

But the real meaning of these numbers is that we are paying for years of underfunding and neglect. We could have ended TB in this country years ago if we had really tried. If we had done so, we would not be facing these new complicated problems.

I do not want to be misunderstood about the blame for this public health problem. Despite the negligence of the administration's budget makers and despite Congressional acquiescence to this negligence, public health and medical workers in the CDC, the States and the voluntary organizations have continued to struggle with TB. They should be commended for their services.

But rather than recognizing that these people and their services need real help, the administration has extended only rhetorical flourishes. Then-CDC Director—now Assistant Secretary—Mason

appeared before this subcommittee 3 years ago. He testified that in his best professional judgment, TB could be eradicated from the United States with a plan that required $36 million a year.

Responding to that testimony, the Congress enacted an authorization of $36 million a year. Neither President Bush nor President Reagan ever requested such money; indeed, until this year, the administration requested that the minimal program now at CDC be repealed and that TB control be left to everyone but the Federal Government.

In April of last year, Secretary Sullivan, in one of his first acts as a member of the Bush administration, promised the American Lung Association that he would work for the eradication of the disease and endorsed a specific three-part plan to do so. But in the budget for 1991, the first budget in which Sullivan took part, the CDC TB program is left with the same nominal support that it received from the Congress in 1990—about one-third of the amount Dr. Mason testified was needed.

We must do better. I hope that, beginning with today's hearing, we can address this disease with the gravity that it deserves. Tuberculosis should have remained a disease of the 19th century. We cannot allow it to be passed on to the 21st century.

[The text of H.R. 4097 follows:]

I

101ST CONGRESS
2D SESSION

H. R. 4097

To amend the Public Health Service Act to extend the program of grants for preventive health services with respect to tuberculosis, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 22, 1990

Mr. WAXMAN (for himself and Mr. ROYBAL) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Public Health Service Act to extend the program of grants for preventive health services with respect to tuberculosis, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Tuberculosis Prevention Amendments of 1990".

SEC. 2. EXTENSION OF PROGRAM OF GRANTS FOR PREVENTIVE HEALTH SERVICES WITH RESPECT TO TUBERCULOSIS.

(a) PROGRAM FOR ELIMINATING TUBERCULOSIS.—Section 317 of the Public Health Service Act (42 U.S.C. 247b) is amended—

(1) in subsection (j)(2), in the first sentence, by striking "preventive health service programs for tuberculosis" and inserting the following: "preventive health service programs for the prevention, control, and elimination of tuberculosis"; and

(2) in subsection (k)(2), in each of subparagraphs (A) through (D), by striking "prevention and control" each place such term appears and inserting "prevention, control, and elimination".

(b) AUTHORIZATION OF APPROPRIATIONS.—Section 317(j)(2) of the Public Health Service Act (42 U.S.C. 247b(j)(2)) is amended in the first sentence by striking "and" after "1989,", and inserting before the period the following: ", and $36,000,000 for each of the fiscal years 1991 through 1993".

Mr. WAXMAN. Our first witness today is Dr. Alan R. Hinman, Director of the Center for Prevention Services at the U.S. Centers for Disease Control. CDC is the Federal agency responsible for administering our Tuberculosis Prevention and Control Program. I want to thank you, Dr. Hinman, for being here today. We have received your written testimony and that will be a part of the record in full.

We would like to ask you to limit your oral presentation to us to no more than 5 minutes. Glad to have you with us.

STATEMENT OF ALAN R. HINMAN, DIRECTOR, CENTER FOR PREVENTION SERVICES, CENTERS FOR DISEASE CONTROL, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY DIXIE E. SNIDER, DIRECTOR, DIVISION OF TUBERCULOSIS CONTROL

Mr. HINMAN. Thank you very much, Mr. Waxman. I am very pleased to be here.

I am Alan Hinman, Director, Center for Prevention Services, Centers for Disease Control. I am accompanied by Dr. Dixie Snider, Director, Division of Tuberculosis Control.

The United States has made considerable progress in reducing the burden of TB. But the disease remains a significant public health problem, with more than 22,000 cases reported in 1988 and a similar number expected in the final figure for 1989. An estimated 10 million Americans are currently infected with TB, and a large majority of new cases occur in this group of persons that are currently infected.

Over the past 30 years from 1953 through 1984, we went through a substantial decline in the reported incidence of TB, and that is shown in figure 1 of my prepared statement. From more than 84,000 cases in 1953 to approximately 22,000 in 1984. However, since 1984 this level has essentially stabilized. We have seen approximately the same number of cases each year since then. We believe that in the period 1985–88 we have had 15,000 cases more than we would have expected had the decline continued.

TB is currently increasing among young blacks and Hispanics, but TB among non-Hispanic whites continues to decline. Much of the recent change relates to the HIV epidemic. There is a strong interaction of HIV infection with tuberculosis infections. And this is a very important issue, but does not in fact account for the majority of TB in the United States.

The majority of persons with TB do not have HIV infection. Among both the HIV infected and the uninfected populations, tuberculosis continues to disproportionately affect the disadvantaged and members of racial and ethnic minority people. Approximately two-thirds of all cases occurred in members of racial and ethnic minorities. Asians were nine times more likely to develop TB than white non-Hispanics, blacks were seven times more likely, Hispanics nearly five times more likely, and Native Americans four times more likely. At least one-third of TB cases occurring in minority group members could have been prevented by current prevention tools.

Notwithstanding these problems, there is good news. The good news is that TB can be eliminated from the United States. The

strategic plan to which you referred has three major components: More effective use of existing prevention and control strategies; the development of new strategies using the current biotechnology and other tools that are now available to us and implementation of these new strategies. We believe this strategic plan can lead to elimination of tuberculosis from the United States by the year 2010.

The tuberculosis cooperative agreements authorized by section 317 of the Public Health Service Act currently provide funding for projects in 46 State, territorial, and metropolitan health departments. The budget maintains the fiscal 1990 funding level of $8.335 million to carry out these programs. These funds are crucial for increasing the effectiveness and efficiency of TB control programs.

The project areas that we are currently supporting include the highest incidence areas. Funds are primarily used to provide operational support and hire outreach workers whose major responsibility is to provide case management services, especially directly observed therapy to persons who would otherwise not likely complete their prescribed treatment regimen. Cure of tuberculosis requires 6 to 9 months of continuous therapy. This is very difficult for many people to complete without the added encouragement provided by these outreach workers.

Section 317 funds are also used to support research activities. In 1989, for example, funds were used to support contracts to study patient compliance issues, analyze the preventability of cases of tuberculosis, obtain laboratory specimens to evaluate new techniques and carry out clinical studies of the developmental drug, Aconiazid, which it is hoped can prevent TB in infected individuals.

In fiscal 1990 we will begin implementation of the three steps of the plan. Once again the programmatic funds will support hiring by State and local departments of more outreach workers to provide therapy and other services to patients. Elimination of tuberculosis from the United States requires committed partnership between the Federal Government, State and local governments, the private sector, volunteer organizations, and patient advocacy groups.

Funds provided under the authority of the act have been very helpful in achieving progress to date and will be equally important in achieving the target of elimination. We would be happy to accept a 5-year simple extension of this authority.

I will be happy to answer any questions that you might have.

[Testimony resumes on p. 18.]

[The prepared statement of Mr. Hinman follows:]

STATEMENT OF

ALAN R. HINMAN, M.D., M.P.H.
DIRECTOR, CENTER FOR PREVENTION SERVICES
CENTERS FOR DISEASE CONTROL

Mr. Chairman and members of the Subcommittee, I am Dr. Alan Hinman, Director, Center for Prevention Services, Centers for Disease Control. I am pleased to appear before the Subcommittee to discuss reauthorization of the Tuberculosis Prevention and Control Program (Section 317(j)(2) of the Public Health Service Act.) With me today is Dr. Dixie E. Snider, Director, Division of Tuberculosis Control

For more than three decades we have had the means to prevent and control tuberculosis (TB). But despite efforts to control this disease, TB remains an important public health problem for the United States and the world.

We estimate that worldwide, each year, 8 million new cases of TB occur and 3 million people die because of this disease. It is estimated that TB is responsible for approximately one-quarter of the preventable deaths in the world. It is one of the most prevalent infections in the world: approximately one-half of the world's population is infected with the tubercle bacillus. The worldwide TB problem has a significant impact on the United States since many of our new cases (22% of reported cases in 1988) occur in foreign-born persons.

The United States has made considerable progress in reducing the burden of TB, but the disease continues to be a significant public health problem as evidenced by the fact that 22,436 new cases were reported to CDC in 1988. Provisional 1989 data indicate that the incidence rate of new cases will approximate that of 1988.

TB is a communicable disease. The causative bacteria (Mycobacterium tuberculosis) are usually spread from person to person through the air. Tiny airborne infectious particles are coughed by a person with untreated, active pulmonary TB. Persons sharing the same airspace with a person with active TB may inhale the infectious particles and become infected.

A healthy immune system usually will keep infected persons from developing TB. However, infected individuals remain at risk of developing active TB, and at any time the organisms may overcome the body's defenses and cause disease. Infection with the human immunodeficiency virus (HIV), which weakens the immune system, is a strong risk factor for developing active TB. I will discuss more about this later.

Left untreated, TB disease can be deadly. Without appropriate treatment, approximately 50 percent of patients will die within 2 years after symptoms appear. Although TB most commonly affects the lungs, disease at other body sites occurs in approximately 15 percent of cases.

An estimated 10 million Americans are currently infected with TB, and the large majority of new cases occurs in this group. From 1953 through 1984, the United States experienced a significant decrease in the number of new TB cases reported -- from more than 84,000 in 1953 to just over 22,000 in 1984 (Figure 1). Since 1984, however, the long-term decline has stopped. Using trend data based on the previous decline, we estimate that from 1985 through 1988 nearly 15,000 excess cases have accumulated (Figure 2).

TB is increasing among young blacks and Hispanics, while TB among non-Hispanic whites continues to decline. Much of the recent change in TB epidemiology is related to the HIV epidemic.

Infection with HIV is having a major impact on the tuberculosis problem. Matching of TB and AIDS registries through 1988 has shown that 4 percent of people with reported AIDS cases also had TB. However, this is only the tip of the iceberg. There are other cases of TB linked to the HIV epidemic. HIV infection can lead to active TB even if the person has not yet developed AIDS. Surveys in Miami, San Francisco, Seattle, and New York revealed that 23 - 42 percent of selected TB patients tested positive for HIV. Nationwide, we conservatively estimate that 5-10 percent of patients with tuberculosis may be infected with HIV. Keep in mind that tuberculosis is a preventable and curable condition even among those with HIV infection. Activities supported through the Public Health Service (PHS) Act Section 317 funding and other CDC and HHS resources are being utilized for these individuals.

Although tuberculosis among HIV-infected persons is an important issue, the majority of persons with TB do not have HIV infection. Among HIV-infected and HIV-uninfected populations, tuberculosis continues to disproportionately affect the socioeconomically disadvantaged and members of racial and ethnic minority populations.

In 1988, approximately two-thirds of all cases occurred in members of minority populations. Asians were 9 times more likely to develop TB than white non-Hispanics; blacks were 7 times more likely, Hispanics nearly 5 times more likely, and native Americans were 4 times more likely. Among children less than 15 years of age, 85 percent of cases occurred in minority group members. At least one-third of TB cases in minority group members could have been prevented by vigorous application of current TB prevention tools.

As I stated earlier, the worldwide tuberculosis problem has significant impact on the United States. In 1988, 22 percent of all persons with TB reported to CDC had been born in another country. Sixty-five percent of foreign-born cases were potentially preventable through preventive therapy.

The elderly are also disproportionately affected by TB. During 1988, 27 percent of cases occurred in the elderly, although this age group makes up only 12 percent of the population. Nursing home residents have higher case rates than the elderly not living in nursing homes, suggesting that TB is being transmitted within these facilities.

Transmission of TB has also been documented in other facilities, such as prisons and shelters for the homeless. A 29-State survey revealed that prison and jail inmates have TB case rates nearly four times the rate among non-incarcerated adults ages 15-64. In addition, data from selected areas show that a relatively high proportion (1.6 to 6.8 percent) of America's homeless have TB, and as many as 50 percent have latent tuberculosis infection.

Notwithstanding these problems, there is good news. The good news is: tuberculosis can be eliminated from the United States! Past prevention and control efforts have resulted in "retreat" of this disease into focal geographic areas and demographically well-defined populations which can be targeted for intensified control and elimination efforts.

In April 1989, Health and Human Services (HHS) Secretary Louis W. Sullivan, M.D., endorsed the goal of eliminating tuberculosis from the United States by the year 2010. Secretary Sullivan said, "It is unacceptable that tuberculosis continues as a public health problem in the United States." With advice and consultation from a large number of persons and organizations, the HHS Advisory Committee for the Elimination of Tuberculosis developed A Strategic Plan for the Elimination of Tuberculosis in the United States. The American Medical Association, the American Lung Association, the American Public Health Association, the American College of Preventive Medicine, and other health care organizations have formally endorsed the plan and are committed to participating in its implementation.

The plan has three major strategies:

1. More effective use of existing prevention and control methods in high-risk target populations.

2. Development and evaluation of new technologies for prevention, diagnosis, and treatment.

3. Rapid assessment and transfer of newly developed technologies into clinical and public health practice.

In support of the strategic plan, the FY 1991 budget contains approximately $21 million in direct funding of TB research and prevention within HHS, an 8 percent increase over the FY 1990 level of $19 million. The budget includes $8.3 million for CDC prevention and control cooperative agreements authorized under Section 317 of the PHS Act; $2.3 million of CDC in-house funds to conduct surveillance, investigate outbreaks, and provide technical assistance; $7.1 million for HIV-related TB demonstration projects, and $3.1 million for NIH funded TB research. In addition, funds appropriated to the Office of Refugee Resettlement and funds in the Preventive Health Services Block Grant are available to States to support TB control.

I would now like to discuss how CDC's Tuberculosis Cooperative Agreement program addresses these strategies.

Tuberculosis cooperative agreements authorized by the PHS Act Section 317, provide funding for projects in 46 State, territorial, and metropolitan area health departments. The budget maintains the FY 1990 funding level of $8,335,000 to carry out this program. These cooperative agreements are crucial for increasing the effectiveness and efficiency of tuberculosis control programs. The project areas include the highest-incidence areas, such as the nation's inner cities. Most of the funds are used to provide operational support and hire outreach workers

whose major responsibility is to provide case management services, especially directly observed therapy to patients who would otherwise be expected not to comply with the prescribed treatment regimen.

Cure of TB requires 6 to 9 months of continuous therapy. Persons who do not faithfully take their medications can continue to spread infection in the community and may develop drug-resistant disease, become chronically disabled, and eventually die from their disease. Although it might be desirable to provide directly observed therapy to all persons with TB, we estimate that at least 20 percent of persons require directly observed therapy to cure their disease and prevent spread of infection. Approximately two-thirds of the outreach workers who provide such therapy and services are hired from the ethnic/cultural populations that they serve.

Some health departments have reported a savings in hospital costs of $3 to $4 for each $1 spent for directly observed therapy. The Institute for Health Policy Studies, University of California, San Francisco, recently evaluated strategies for treating TB patients and concluded: " The management strategy of choice is directly observed therapy. This is especially true in patients with identified problems, but is justifiable on a cost-effectiveness basis for all patients."

In addition to the outreach activities discussed, up to 10 percent of cooperative agreement funds are used for various educational, training, and research activities. Recently, new health care provider educational materials have been developed. CDC and the American Thoracic Society have begun a National Tuberculosis Training Initiative in collaboration

with 22 national medical and nursing organizations. Plans to increase knowledge about TB among U.S. health care providers are well underway. A Core Curriculum on Tuberculosis, which will aid the participating organizations in preparing and planning educational activities, has been developed and is planned for distribution in late FY 1990.

PHS Act Section 317 funds are also used to support research activities. For example, in FY 1989, funds were used to support contracts to study patient compliance issues, analyze preventable cases, purchase laboratory specimens needed to evaluate new diagnostic techniques, and to perform clinical studies of a developmental drug, Aconiazid, which it is hoped can be used in preventing the development of TB in infected individuals.

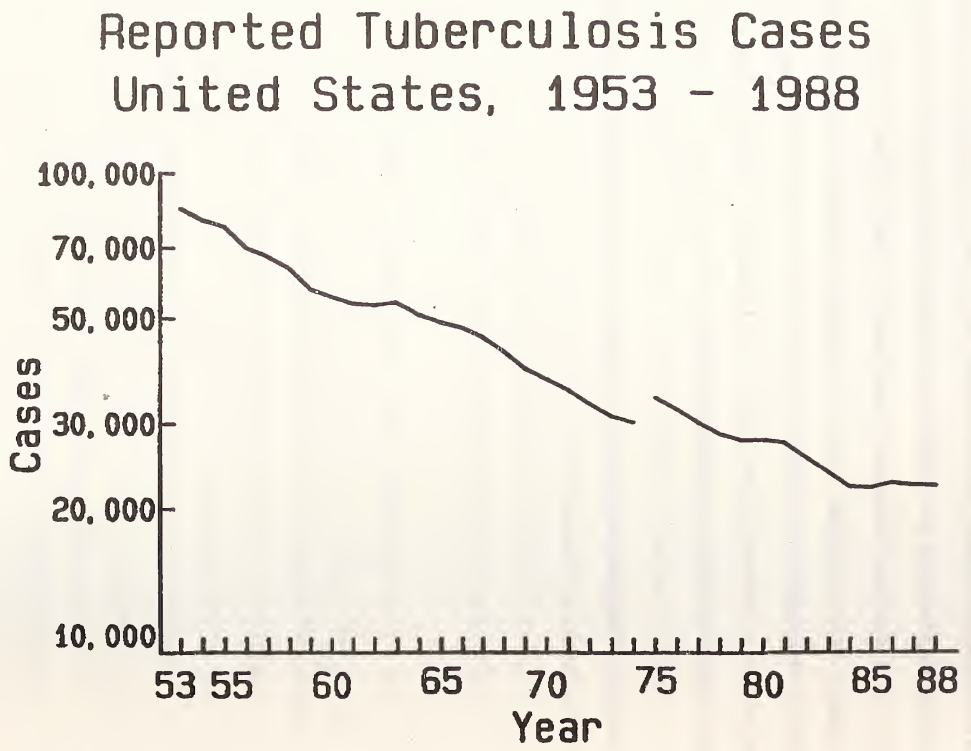
In FY 1990, CDC will begin implementation of the three steps of the TB Elimination Plan. Programmatic funds will principally support the hiring by State and local health departments of more outreach workers to provide directly observed therapy and other services to patients. Preliminary research will be initiated on new diagnostic and treatment methods, and technology transfer will be encouraged through support of experienced program managers requested by States and cities. Funds will also support a limited number of laboratory courses conducted for State and local technicians, and provide development of new training and educational materials for targeted audiences.

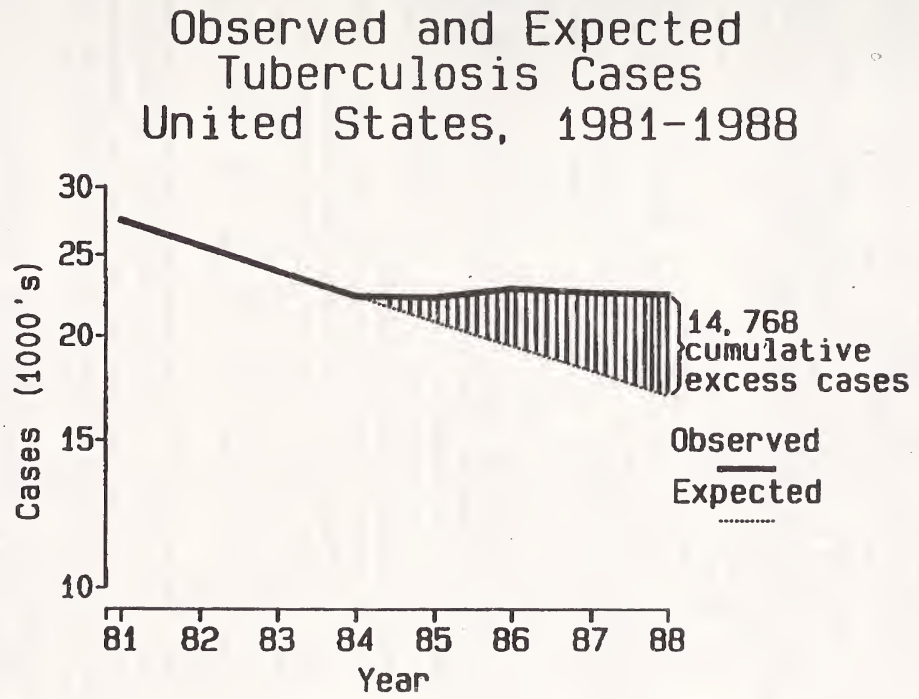
In addition, cooperative agreement funds will continue to play an important role in achieving other national objectives such as reducing health care costs, increasing minority employment, and building capacity within State and local health departments.

Elimination of tuberculosis from the United States requires a committed partnership between the Federal government, State and local governments, the private sector, voluntary organizations, and patient advocacy groups. Funds provided under the authority of PHS Act Section 317 have been very helpful in achieving progress to date and will be equally important in achieving the target of elimination. We would accept a five year simple extension of this authority.

I would be happy to answer any questions that you or other members of the Subcommittee may have.

FIGURE 1


Reported Tuberculosis Cases
United States, 1953 - 1988
100,000
70,000
50,000
30,000
20,000
10,000
Cases
53 55 60 65 70 75 80 85 88
Year


Observed and Expected
Tuberculosis Cases
United States, 1981-1988
30
25
20
15
10
Cases (1000's)
14,768
cumulative
excess cases
Observed
Expected
81
82
83
84
85
86
87
88
Year

Mr. WAXMAN. Dr. Hinman, you stated in your remarks that despite the disappointing statistics you presented to us today, "there is good news that . . . Tuberculosis can be eliminated from the United States." Is this news? Isn't this exactly what Dr. Mason told us in 1987? My question is what progress have we made in reaching this goal?

Mr. HINMAN. I think, Congressman, in response there have been a number of additional studies undertaken and additional support given to the Cooperative Agreement Program. There have been now two major conferences addressing research needs in tuberculosis. The NIH is providing additional emphasis on TB research.

Mr. WAXMAN. So we have some conferences and some new research, but in terms of cases of TB, we can't say that real progress has been made, can we?

Mr. HINMAN. No, we can not.

Mr. WAXMAN. The numbers you have given us, almost 23,500 new cases in 1988 and 1989, indicate that we are far from reaching the goal. Should we be further along in eradicating this disease from the United States? What is slowing down our progress?

Mr. HINMAN. Well, sir, I think one can always say that if we were able to provide more of the directly observed therapy this would help us greatly. The persons who are unwilling or unable to complete therapy on their own represent a continuing challenge of transmission, and we believe that this is an area where additional efforts would be desirable.

In addition, of course, the new tools would be very useful, that is through additional research activities.

Mr. WAXMAN. Is the problem getting the people who are infected with TB through their treatment of 6 to 9 months?

Mr. HINMAN. This is a serious problem because people who have tuberculosis typically begin feeling better very soon after they begin therapy, and then they may not be as highly motivated, particularly if they have other concerns such as being homeless or drug users.

Mr. WAXMAN. TB disproportionately affects those with low incomes and members of ethnic and racial minority populations. Wouldn't you say that in order to reach that population and continue to push them into completing their treatment or coming in for treatment, that we are going to need funding for outreach beyond what we already have?

Mr. HINMAN. We estimate that approximately 20 percent of the persons with tuberculosis actually would substantially benefit from receiving directly observed therapy. We are currently providing such therapy, we estimate, to about 10 percent of the persons.

Mr. WAXMAN. I was pleased to see last year that Dr. Sullivan endorsed the goal of eliminating TB from the United States by the year 2010. I am pleased to learn today that CDC has begun to implement a three-part strategy designed to meet that goal. Are all three strategies now in place?

Mr. HINMAN. The third strategy, of course, is in many ways a future strategy, because it involves implementing the new tools as they are developed. We have begun implementation of the first two elements of the strategy.

Mr. WAXMAN. For fiscal year 1991, I understand the administration is proposing that CDC be given $8 million for the prevention and control grants to States as part of this three-part elimination plan. Yet in 1987, when Dr. Mason testified before our subcommittee, he told us it would take almost $24 million in fiscal year 1990 to have such a program up and running at full speed. How can we hope to reach Dr. Sullivan's goal by the year 2010 if the TB program is operating with just one-third of the funds needed to do the job?

Mr. HINMAN. It will be difficult.

Mr. WAXMAN. Is $36 million still the figure CDC estimates is needed to carry out the TB Eradication Program? Will you submit a version of the 1987 chart of the summary of estimated costs?

Mr. HINMAN. We will be pleased to submit it.

[The information follows:]

The elimination of tuberculosis from the United States will require a committed partnership between the Federal Government, State and local governments, the private sector, voluntary organizations, and patient partnerships. At the Federal health level, CDC, FDA, NIAID, the Health Resources and Services Administration, the Indian Health Service, and the Office of Refugee Health must continue to work together to achieve TB elimination.

CDC's professional judgment of the estimates of the CDC costs are given in the table below which presents updated fiscal data in a revised format. CDC is not requesting additional funds for TB elimination at this time because of fiscal constraints imposed by the Federal deficit and the need to allocate available funds to other high-priority programs including, for example, vaccines and immunizations.

CDC COSTS

[In millions of dollars]

	Year 1	Year 2	Year 3
Current programs	[1] 10.7	11.1	11.5
Additional required	25.3	26.3	27.4
Elimination plan total	36.0	37.4	38.9

[1] Includes continuation funding of $2.3 million for in-house operations and $8.4 million for TB Prevention and Control Cooperation Agreements. Does not include $6.8 million for TB/HIV control demonstration projects.

Mr. HINMAN. We estimate that full implementation of the plan through the Cooperative Agreement Program would entail approximately $36 million.

Mr. WAXMAN. As I understand it, one of the principal activities of the TB program is to hire outreach workers whose major responsibility is to provide directly observed therapy to otherwise noncompliant patients. You state in your testimony that CDC estimates that at least 20 percent of the patients require directly observed therapy to cure their disease and to prevent spread of infection. Is the TB program currently providing that therapy to the 20 percent of the patients who require it?

Mr. HINMAN. We estimate that approximately 10 percent of these patients are receiving directly observed therapy.

Mr. WAXMAN. What happens to those patients who need therapy who don't get it?

Mr. HINMAN. Some of them will complete it on their own and some will discontinue therapy.

Mr. WAXMAN. They are at risk of dying themselves or spreading the disease to others?

Mr. HINMAN. Yes.

Mr. WAXMAN. As you noted in your remarks, the vast majority of TB cases—approximately two-thirds in 1988—occur in members of minority populations.

Does any of the TB research indicate why minorities are more susceptible to this disease? I know that minority populations are more disadvantaged than other groups and that this factor helps account for a great deal of the disease, but are there additional reasons that may help explain why TB is so prevalent among Asians, blacks, Hispanics and Native Americans?

Mr. HINMAN. For many years it has been thought that the primary reason for the increased risk of TB noticed among minority populations was merely related to socioeconomic status. A recent paper published in the New England Journal of Medicine by Dr. Stead indicates that there are factors beyond socioeconomic status and I would ask Dr. Dixie Snider to answer your question in more detail.

Ms. SNIDER. The paper that Dr. Stead published in the New England Journal of Medicine suggests that at least blacks among the minority groups might be at increased risk of acquiring infection given the same amount of exposure. There is some laboratory work that has been done which is supportive of this. Although we consider this evidence preliminary, it is intriguing. I think it has implications for what we can expect in the future with regard to tuberculosis incidence rates among our black citizens unless we take more aggressive action to reduce transmission and prevent the disease in that particular population.

Mr. WAXMAN. Do you have any breakdown as to whether the disease is more prevalent among blacks based on economic class, Dr. Snider?

Ms. SNIDER. Yes, among all racial ethnic groups there is an inverse relationship between socioeconomic class and incidence of tuberculosis. We recently have done an analysis with nationwide data. Dr. Hinman has looked at this particular factor in New York State and I believe his analysis has shown the same thing.

Mr. WAXMAN. You stated that in 1988, one-third of TB cases in minorities could have been prevented "by vigorous application of current tools" and that 65 percent of the foreign-born cases were "potentially preventable through therapy." What kinds of prevention tools and preventive therapy are we talking about?

Mr. HINMAN. For the foreign-born this would involve knowledge at the time of entry into the United States of their tuberculosis infection status, and then providing preventive therapy. For the minority populations currently in the United States, it would relate to more aggressive investigation of cases, identification of those who are currently infected but not yet ill with tuberculosis, and assuring that they complete a course of preventive therapy.

Mr. WAXMAN. Does the CDC recommend that all persons who test positive on a TB skin test or who are diagnosed with TB be counseled and tested regarding AIDS and HIV?

Mr. HINMAN. We currently recommend that persons who have tuberculosis should be counseled and tested and persons who are infected be also offered counseling and testing.

Mr. WAXMAN. Is this because TB is associated strongly with AIDS?

Mr. HINMAN. TB and HIV are closely intertwined.

Mr. WAXMAN. Would you submit for the record the expected cost of counseling and testing for HIV all of the TB patients that you would reach with your TB elimination plan?

Mr. HINMAN. Yes.

[The information follows:]

CDC estimates that when the TB Elimination Plan is fully implemented, approximately 245,000 individuals would be identified as testing positive on a TB skin test, for which CDC would recommend HIV counseling and testing. This includes all active TB cases (22,500 persons); TB suspects (22,500 persons who have a TB diagnosis pending); and other persons with TB infection (200,000 tuberculin reactors). If all of these individuals received HIV counseling and testing, the cost would be approximately $11.4 million. We estimate however that a substantial number of these 245,000 TB-infected individuals are being reached through current HIV counseling and testing activities in the Nation, including those funded through drug abuse clinics, State and local health departments, the private sector, and, CDC-supported State HIV/AIDS prevention programs, and TB/HIV control demonstrations.

Mr. WAXMAN. If you identify a patient as being HIV positive also, would the CDC recommend further diagnostic measures such as T-cell tests?

Mr. HINMAN. In general it is recommended that TB patients should undergo testing and be monitored.

Mr. WAXMAN. Would you submit for the record the expected cost of performing such diagnostic measures on the HIV-positive persons that you would reach with your TB elimination plan?

Mr. HINMAN. Yes.

[The information follows:]

HIV-seroprevalence surveys in metropolitan areas, where approximately 25 percent of TB cases and suspects in the U.S. are served, suggest that annually 2,600 TB cases and suspects in these areas would be HIV seropositive if tested. Although HIV-seropositivity levels in other areas of the country are not known, it is estimated that another 2,600 HIV seropositive cases and suspects will be identified annually. Among the estimated 200,000 tuberculin reactors expected to be identified through intensified TB elimination efforts when fully implemented, it is estimated that 2 percent, or 4,000, will be seropositive. This would bring the total TB and HIV-seropositive cases to 9,200. CDC guidelines (*MMWR,* Volume 38, 85, June 16, 1989) recommend monitoring CD4+ lymphocyte percentages or counts in HIV-infected persons at least every 6 months to see if they are eligible for prophylactic treatment. If CD4+ testing were implemented to all of these individuals, the expected total costs of these tests, including monitoring and analyzing test results, would be about $1.4 million annually. This figure represents an estimated 13,984 CD4+ tests at $100 per test. Funding for such diagnostic measures could be expected to be shared by State and local governments, the private sector through private insurers and through the Federal Government.

Mr. WAXMAN. If you identify a person as being HIV positive with a T-cell count of 200 or under, would CDC recommend other treatment measures in addition to TB treatment?

Mr. HINMAN. It is recommended that persons with such cell counts would benefit either from AZT or from pentamadine prophylaxis or both.

Mr. WAXMAN. Would you submit the expected cost of performing such treatment measures on the HIV-positive person that you would reach with your TB elimination plan.

Mr. HINMAN. Yes.

[The information follows:]

CDC estimates that 58 to 64 percent of persons with HIV-infection may have CD4+ counts of <500/mm. This would mean that of the 9,200 TB-infected patients who are estimated to be HIV-seropositive, at the high end, 5,888 would have CD4+ counts of <500/mm and be eligible for zidovudine (AZT) treatment. If all of these persons received AZT treatment, this would be expected to cost about $23.6 million for the costs of the drug alone. In addition, 17 to 19 percent of the 9,200 patients would have CD4+ counts of <200/mm and would be eligible for pentamidine treatment at a cost of about $3.1 million. These estimates do not take into account the anticipated development of other, potentially less expensive drug therapies for HIV/AIDS infection. Funding for such treatments would be expected to be shared by State and local governments, private insurers and others, and by the Federal Government, where the patients qualify as beneficiaries under Medicare and Medicaid programs.

Mr. WAXMAN. All of these public health service recommendations about AIDS and TB-HIV counseling and testing, T-cell testing, early intervention drugs—there must be a considerate expense to people and clinics and States that are trying to address TB control on what we all agree is an inadequate budget. How can such doctors and clinics adopt the CDC recommendation about AIDS without eroding their original efforts of TB control? Are we forcing TB doctors to choose between controlling TB and controlling AIDS?

Mr. HINMAN. We are providing additional support for the HIV prevention cooperative agreements to support counseling and testing in TB clinics. That does not speak overall to further issues of referral and followup, but it does at least provide support for counseling and testing activities.

Mr. WAXMAN. Funds in addition to what they would give the Tuberculosis Control Program?

Mr. HINMAN. Yes. These are funds coming from HIV cooperative agreements.

Mr. WAXMAN. Would those additional funds cover diagnostic treatment for those individuals?

Mr. HINMAN. No, sir. They support counseling and testing. They do not provide support for the continuing monitoring and followup.

Mr. WAXMAN. So there are additional funds for the testing only but—and the counseling?

Mr. HINMAN. That is correct.

Mr. WAXMAN. But not beyond that further diagnosis?

Mr. HINMAN. To date our HIV prevention cooperative agreements have not been very effectively used in support of followup activities.

Mr. WAXMAN. I appreciate your testimony and look forward to receiving those additional items for the record. We look forward to working with you.

Mr. HINMAN. Thank you very much, Congressman.

Mr. WAXMAN. The three witnesses on our second panel have long been involved with TB prevention and control.

Dr. Lee B. Reichman and Dr. George W. Comstock are testifying today on behalf of the American Lung Association and the American Thoracic Society. Dr. Reichman is professor of medicine at the University of Medicine and Dentistry in New Jersey. Dr. Comstock is a professor of medicine at the Johns Hopkins School of Hygiene and Health. And representing the American Public Health Associa-

tion is Dr. William Banton II, medical consultant to the Missouri Department of Health.

We want to welcome the three of you to our subcommittee hearing this morning. Your prepared statements will be in the record in full. We would like to ask, however, that you limit your oral presentation to us to no more than 5 minutes.

STATEMENTS OF LEE REICHMAN, PROFESSOR OF MEDICINE, UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY, ON BEHALF OF AMERICAN LUNG ASSOCIATION/AMERICAN THORACIC SOCIETY, ACCOMPANIED BY GEORGE COMSTOCK, PROFESSOR OF EPIDEMIOLOGY AT JOHNS HOPKINS SCHOOL OF HYGIENE AND PUBLIC HEALTH; AND WILLIAM C. BANTON II, MEDICAL CONSULTANT, MISSOURI DEPARTMENT OF HEALTH, ON BEHALF OF AMERICAN PUBLIC HEALTH ASSOCIATION

Mr. REICHMAN. Thank you, Mr. Chairman.

I am Lee Reichman, professor of medicine at University of Medicine and Dentistry of New Jersey, Newark, NJ. With me is Dr. George Comstock, who is past chairman of the CDC National Advisory Committee for the Elimination of Tuberculosis, and professor of epidemiology at Johns Hopkins.

It is a great honor for me to appear with Dr. Comstock, who is my mentor, and was my professor when I received my master's degree in public health at Johns Hopkins in 1971.

As you know, Mr. Chairman, the American Lung Association is our Nation's oldest voluntary health organization, established in 1904 as the National Association for the Study and Prevention of Tuberculosis. The ALA remains committed to its original goal, the elimination of tuberculosis, while expanding its mission to address the greater challenge of the prevention, treatment and control of all lung diseases.

At the outset, the American Lung Association would like to thank you and the subcommittee for the opportunity to appear before you today to discuss the reauthorization of the Tuberculosis Grant Program and the relationship of the Strategic Plan for the Elimination of Tuberculosis to this program.

First, we want to express our deep gratitude for the subcommittee's continued support of the Project Grants for Preventive Health Projects for Tuberculosis administered by the Centers for Disease Control. This program was reauthorized in 1987 with an important new component added to that authority, the provision of research activity.

Secretary of Health and Human Services Louis Sullivan has publicly endorsed the recommendations made by the Advisory Committee for the Elimination of Tuberculosis. In his speeches, Secretary Sullivan has firmly established the goal of tuberculosis elimination as Bush administration policy. The American Lung Association strongly applauds this commitment by the executive branch.

The American Lung Association appears today to again recommend that the subcommittee expand the commitment to tuberculosis elimination and add two critical provisions to the existing statute.

First, due to the importance of the Project Grant Program within the Strategic Plan for the Elimination of Tuberculosis, section 317 should be renamed "Grants for the Elimination of Tuberculosis." This would clearly state that U.S. policy is to eliminate tuberculosis by the year 2010.

Second, the Advisory Committee for Elimination of Tuberculosis charged with the development of the Strategic Plan for the Elimination of TB should be statutorily established. This would allow the continuation of this important body to monitor the progress made to eliminate TB, and to make periodic recommendations on needed adjustments to the plan. The committee would also make recommendations to Congress.

It is important that the current authorization for the project and other grants be continued. We recommend a continuing authorization level at $36 million for fiscal years 1991, 1992, and 1993.

Now, Dr. Comstock will comment further on our recommendations. Thank you.

STATEMENT OF GEORGE COMSTOCK

Mr. COMSTOCK. Thank you.

Thank you, Mr. Chairman.

To stress the importance of the Grant Program for tuberculosis control with the emphasis on the goal of elimination of tuberculosis, the American Lung Association endorses the recommendation of the Advisory Committee to Eliminate Tuberculosis that the United States establish the goal of tuberculosis elimination by the year 2010 at a case rate of less than one per million, with an interim target of 3.5 per 100,000 population by the year 2000.

An expanded Tuberculosis Control Program effort, as recommended by the Committee for the Elimination of Tuberculosis, would not only prevent the majority of tuberculosis cases in the United States but would also save health care dollars. It is estimated that without full implementation of the plan, elimination of tuberculosis will not be achieved until as late as 2072.

More than 664,000 cases of tuberculosis will be reported in this period and of these cases, 64 percent would be preventable. In 1988 dollars, the prevention of more than 426,000 cases would represent a savings of approximately $6.1 billion.

You have heard from Dr. Hinman that in contrast to the steady decline in tuberculosis cases reported each year prior to 1984, there has been essentially no decline since that time. In view of this fact, you may wonder why we are talking about tuberculosis elimination.

As far as we can tell, case rates have ceased to fall for two main reasons. One is the gradual cutback in tuberculosis control activities that have occurred over much of the preceding decade. The other is the impact of the AIDS epidemic.

Fortunately, the AIDS epidemic can be an ally as well as an enemy of tuberculosis control if we recognize our opportunities and take advantage of them. Let me give a quick explanation.

To eliminate tuberculosis expeditiously, we need better ways to identify persons whose bodies still harbor living tubercle bacillus and better regiment. Both are at hand, and with continuing re-

search support, even better ones should be forthcoming. But before new testing and treatment procedures can be wisely adopted, they must be given scientifically controlled trials to see if they are better than the old. To do this requires a population at high risk of developing tuberculosis. The higher the risk, the quicker an answer can be obtained.

Persons who have been infected with tubercle bacillus and AIDS have a risk of developing tuberculosis that is greater than any group we have ever known before. In this country, the major group with both infections is the intravenous drug users. This can be carried out but the United States, but in much of the sub-Saharan Africa, Brazil and Haiti, there are much larger numbers of dually infected persons.

The World Health Organization has just held an informal consultation on this problem and has endorsed the critical need for studies of preventive treatment among dually infected persons.

They have also identified a number of research groups who have developed protocols and are looking for funding. By investing relatively small amounts of money in preventive trials in high-risk countries, we can obtain answers much more quickly than we can at home. The results can be applied both abroad and at home. Abroad primarily to dually infected persons and at home primarily to persons infected only with tubercle bacilli.

Quick answers abroad will lead to quick answers at home. Persons infected with tubercle bacillus are of great importance because they comprise a seed bed from which future cases of tuberculosis will continue to sprout. We have within our grasp the means of reducing the seeds in the seed bed and preventing tuberculosis at its source. With the combination of national and international research and with the revitalization of our tuberculosis control activities, we can indeed eliminate tuberculosis quickly and with benefit to all.

Thank you for your attention, sir.

Mr. WAXMAN. Thank you.

[The prepared statement of the American Lung Association/American Thoracic Society follows:]

PREPARED STATEMENT OF THE AMERICAN LUNG ASSOCIATION/AMERICAN THORACIC ASSOCIATION

Mr. Chairman, members of the subcommittee, I am Dr. Lee Reichman, Professor of Medicine at the University of Medicine and Dentistry of New Jersey in Newark. With me today is Dr. George Comstock, past Chairman of the Center for Disease Control Advisory Committee for Elimination of Tuberculosis and Professor of Epidemiology at Johns Hopkins School of Hygiene and Public Health. We are appearing here today as representatives of the American Lung Association and its medical section, the American Thoracic Society.

The American Lung Association is this nation's oldest voluntary health organization, established in 1904 as the National Association for the Study and Prevention of Tuberculosis. The ALA remains committed to its original goal—the elimination of tuberculosis—while expanding its mission to address the greater challenge of the prevention, treatment and control of all lung diseases.

At the outset, the American Lung Association would like to thank you and the subcommittee for the opportunity to appear before you today to discuss the reauthorization of the Tuberculosis Grant Program and the relationship of the Strategic Plan for the Elimination of Tuberculosis to this program. Most importantly, we want to express our deep gratitude for the subcommittee's continued support of the Project Grants for Preventive Health Projects for Tuberculosis administered by the

Centers for Disease Control. This program was reauthorized in 1987 with an important new component added to that authority, provision of research activity.

Secretary of Health and Human Services Louis Sullivan has publicly endorsed the recommendations made by the Advisory Committee for Elimination of Tuberculosis. In speeches, Secretary Sullivan has firmly established the goal of tuberculosis elimination as Bush Administration policy. The American Lung Association applauds this commitment by the executive branch.

The American Lung Association appears today to again recommend to the subcommittee to expand the commitment to tuberculosis elimination and add two critical provisions to the existing statute.

First, due to the importance of the Project Grant Program within the Strategic Plan for Elimination of Tuberculosis, Section 317 should be renamed "Grants for the Elimination of Tuberculosis." This would clearly state that U.S. policy is to eliminate tuberculosis by the year 2010.

Second, the Advisory Committee for Elimination of Tuberculosis charged with the development of the Strategic Plan for the Elimination of TB should be statutorily established. This would allow the continuation of this important body to monitor the progress made to eliminate TB, and make periodic recommendations on needed adjustments to the Plan. The committee would also make recommendations to Congress.

It is important that the current authorization for project and other grants be continued. We recommend a continuing authorization level at $36 million for fiscal years 1991, 1992, and 1993. The American Lung Association is very concerned with the funding levels for TB elimination.

Now, Dr. Comstock will comment further on the American Lung Association's recommendations.

TUBERCULOSIS MORBIDITY

Although tuberculosis is a preventable and curable disease, it persists as a public health problem in the United States and the world. When the U.S. Public Health Service was created in 1944, there were 126,000 cases of tuberculosis reported in that year. As a result of tuberculosis control efforts, between 1953 and 1984 the number of cases reported decreased annually at an average of 5 percent.

However, during the past 4 years there has been marked swings in the tuberculosis case rate in this country. This represents a serious destabilization in our ability to continue decreasing the occurrence of tuberculosis. For instance, the rate of decrease continued in 1985 at a pace of 0.2 percent. In 1986 we witnessed a 2.6 percent increase in the number of cases. In 1987, we saw a 1.1 percent decrease. And in 1988 there was a decrease of 5.7 percent in the number of cases reported. The implications of this inconsistency are placed right at the doormat of the research and development community.

Worldwide, the tuberculosis problem is enormous. Perhaps as many as one-half of the persons on earth are infected with *Mycobacterium tuberculosis.* Estimates of the current tuberculosis morbidity and mortality range from a prevalence of 10 to 30 million cases of active disease, an incidence of 3.5 million new cases and 3 million deaths annually.

Today, marked increases in tuberculosis in the United States occur in certain specific populations including:

(1) Persons infected with the human immunodeficiency virus: HIV infection appears to have increased the incidence of tuberculosis by causing immunosuppression which allows latent tuberculous infection to progress to clinically apparent disease.

(2) Minorities: nearly two-thirds of the cases now occur among racial and ethnic minorities. The case rate is consistently higher for nonwhites—29 per 100,000 compared to 5.6 per 100,000 in 1985. Over 84 percent of cases in nonwhites can be considered excess cases.

(3) Children: 1,134 cases were reported in children under 15 years of age in 1988 and 687 cases were reported in children under 5 years of age. More than 55 percent of cases in children in 1988 occurred in minority groups.

(4) The elderly: among all racial or ethnic groups and both sexes, the tuberculosis case rate is highest in the elderly. The majority of cases occur among the 95 percent of elderly persons who live in the community, although the case rate is higher among the elderly living in long-term care facilities.

(5) The foreign-born: tuberculosis is very common among immigrants, refugees, and migrant workers from high prevalence countries. In 1986, tuberculosis cases among the foreign-born represented 22.6 percent of all tuberculosis cases reported, 22.9 percent of the cases reported in 1988. Nearly 60 percent of foreign-born cases

occur in persons less that 35 years of age at the time of arrival in the United States and are potentially preventable.

STRATEGIC PLAN FOR THE ELIMINATION OF TUBERCULOSIS IN THE UNITED STATES

In 1987 the Advisory Committee for the Elimination of Tuberculosis was established within the Department of Health and Human Services to provide recommendations for the development of new technology, application of prevention and control methods, and management of state and local tuberculosis programs aimed at the elimination of tuberculosis. The American Lung Association endorses the committee's recommendation that the United States establish the goal of tuberculosis elimination by the year 2010 at a case rate of less than 0.1 per 100,000 population, with an interim target of a case rate of 3.5 per 100,000 population by the year 2000.

An expanded Tuberculosis Control Program effort, as recommended by the Committee for the Elimination of Tuberculosis, would not only prevent the majority of tuberculosis cases in the United States but also save health care dollars. It is estimated that without full implementation of the Plan, elimination of tuberculosis will not be achieved until as late as 2072. More than 664,000 cases of tuberculosis will be reported in this period and of these cases, 64 percent would be preventable. In 1988 dollars, the prevention of more than 426,000 cases would represent a savings of approximately $6.1 billion.

In conclusion, the changes in the authority and the funding levels the American Lung Association recommends are critical to achieving the elimination of tuberculosis in the United States by the year 2010. Thank you for the opportunity to appear today. We welcome your questions.

Mr. WAXMAN. Dr. Banton.

STATEMENT OF WILLIAM C. BANTON II

Mr. BANTON. Yes. Mr. Chairman and Mr. Nielson, again, it is a pleasure to be here.

As Dr. Reichman pointed out, we are particularly happy that we are with our previous professor, Dr. Comstock, who was our professor at Johns Hopkins. I was particularly pleased and honored to have worked with him as the first—he was the first chair of the Centers for Disease Control Advisory Committee for the Elimination of Tuberculosis.

At the present time, I am medical consultant for the Missouri Department of Health and the present chair of the Centers for Disease Control Advisory Committee for the Elimination of Tuberculosis. Today I am representing the American Public Health Association. I am very pleased to have the opportunity to appear before the subcommittee to discuss reauthorization of the Tuberculosis Prevention and Control Program.

This program is an essential element in the successful elimination of tuberculosis from our country. Tuberculosis, a 7,000-year-old disease, currently infects just about one half of the 5 billion people that are here on planet Earth, making it the most prevalent infection in the world. Today there are 6 to 10 million new active cases worldwide with 3 million deaths.

In this country at the turn of the century, it was the No. 1 cause of death. The advent of effective antituberculosis drug therapy in the late 1940's and early 1950's displaced tuberculosis as No. 1 cause of death and made it the preventable and curable disease that it is today.

However, we still have over 20,000 new, active cases reported each year with over 1,700 deaths and 10 million persons infected with tuberculosis in the United States of America.

In 1953, when nationwide reporting was first implemented, there were 84,304 cases. There was a 5 percent decline in tuberculosis incidence between 1953 and 1984. In 1985, this incidence started to climb again. It is theorized that this is probably due to the HIV infection epidemic and possibly other immunosuppressive infections, along with the increased use of various immunosuppressant drugs.

Of great concern to the American Public Health Association is that during the past 20 to 30 years, there have been marked differences in morbidity trends between our white majority and our nonwhite minority populations. Incidence rates in minorities have been much higher and have declined much more slowly. In 1953, the incidence in nonwhites was 126 per 100,000, compared to 44 in whites, for a rate ratio of 2.9. In 1987, the rates were 29.4 and 5.61 respectively, for a rate ratio of 5.3.

Of the 22,517 tuberculosis cases reported to CDC in 1987, approximately 14,000 or 64 percent occurred in racial and ethnic minorities, including 36 percent in blacks, 16 percent in Hispanics, 11 percent in Asians/Pacific Islanders, and 1.4 percent in American Indians/Alaskan Natives. In relation to the incidence rate of 4.3 per 100,000 in non-Hispanic whites, the incidence rate in Asian/Pacific Islanders is more than 11-fold higher; in non-Hispanic blacks, it is more than sixfold higher; in American Indians/Alaskan Natives, it is nearly fivefold higher; and in Hispanics it is more than fourfold higher.

Reported tuberculosis cases in children under 15 years have had an average annual decline of about 6.3 percent, from 5,985 cases in 1962 to 1,177 cases in 1987.

From 10 per 100,000 population in 1962 to 2.3 in 1987, case rates have declined at about the same rate among whites and nonwhites—but case rates in nonwhites have stayed consistently well above those in whites. In 1987, the rate among nonwhite children was nearly five times the rate among white children, 6.2 versus 1.3.

In 1987, of all cases, 19 percent were non-Hispanic whites; 36 percent were non-Hispanic blacks; 15 percent were Asian/Pacific Islanders; 2.9 percent were American Indian/Alaskan Natives; and 27 percent were Hispanics.

Thus, 80 percent of all tuberculosis in children occurred in racial and ethnic minorities.

Yes, overall, two-thirds of the tuberculosis high-risk problem is among minorities and 80 percent of childhood tuberculosis is among racial and ethnic minorities.

And step 1 of the tuberculosis elimination plan recognizes the critical importance of our high risk minority populations and outlines specific action approaches. Step 1 is: The more effective use of current prevention and control measures, especially in high-risk target populations.

Let me say a word about the strategic plan. It began in 1984 and was endorsed and authorized by the Secretary of the Department of Health and Human Services, Dr. Louis Sullivan, in 1989. It has a goal of eliminating tuberculosis from the United States by the year 2010. It is a good, realistic plan containing three basic parts or steps. It has had input from literally thousands of scientists, experts and tuberculosis advocates. It remains open and flexible, but

it has structured objectives with relevant time schedules. It is logical, straightforward, not complicated and easy to understand.

The plan is comprehensive and recognizes that no one agency, public or private, no one group of people alone can achieve tuberculosis elimination. Success requires a coalition of many agencies and population groups in our society. Most of our problem health issues have high-risk target populations that are the same. Thus, it makes good sense for efficiency and economy to build coalitions among agencies and programs to achieve the common good.

As a matter of fact, the plan addresses the needs and responsibilities of eight specific groups in our society that must be involved and committed for us to achieve success in the implementation of the plan. The Federal Government is one of the groups. The others are: health care providers, both private and public sectors; State and local governments; academic centers; private enterprise; voluntary health and professional agencies such as the American Public Health Association and the American Lung Association; the general public; and yes, the tuberculosis patient.

It is important to remember that those minorities that are high risk are the socioeconomically disadvantaged and are greatly dependent upon governmental support. They are greatly dependent upon the reauthorization of the Tuberculosis Prevention and Control Program.

The American Public Health Association feels that this elimination plan will be successful and prevent illness, save lives, and save money if fully implemented by all of the societal components that I have mentioned. On the other hand, if not implemented, particularly in the reauthorization of the Tuberculosis Prevention and Control Program, the TB problem will continue to increase and become more difficult to control and become much more costly to our taxpayers in the future.

Funds provided under the authority of the Public Health Service Act, section 317, represents a critical component to the successful elimination of tuberculosis from our country by the year 2010. The American Public Health Association strongly requests continued authorization of this program.

Thank you.

[The charts attached to Mr. Banton's prepared statement follow:]

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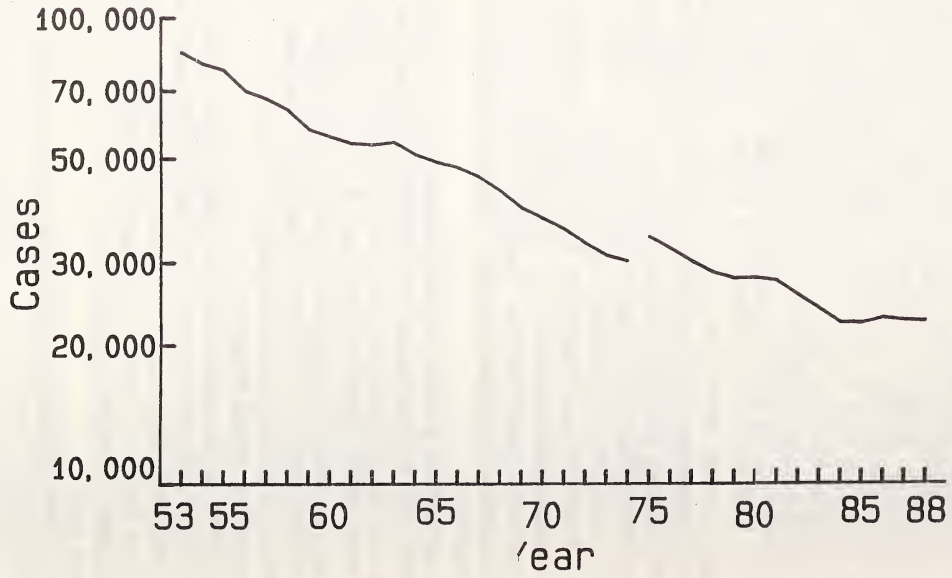
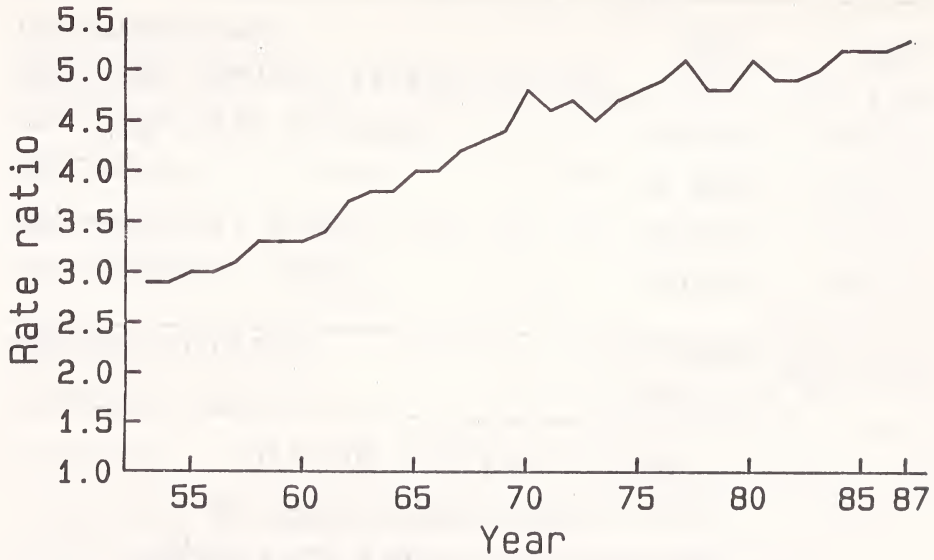
Reported Tuberculosis Cases
United States, 1953 - 1988



Ratio of Reported Tuberculosis Case Rates,* Non-White: White, United States, 1953-1987



*Rate per 100,000 population

Reported Tuberculosis Cases By Race And Ethnicity United States, 1987

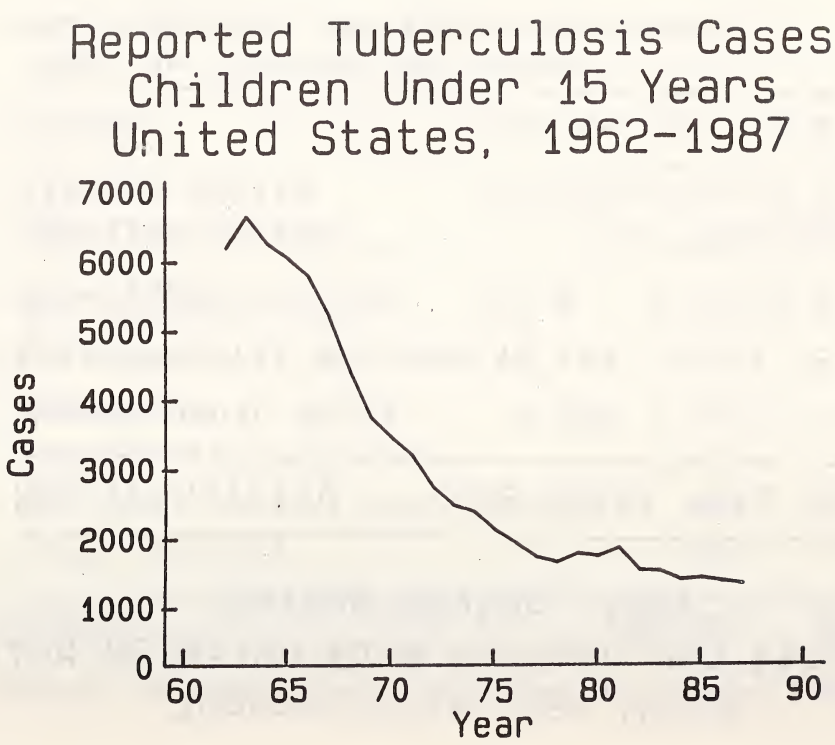
Race/Ethnicity	Number Of Cases	Percent
Non-Hispanic White	8,048	35.7
Non-Hispanic Black	8,067	35.8
Hispanic	3,485	15.5
Asian/Pacific Islander	2,477	11.0
American Indian/Alaskan Native	317	1.4
Other/Unknown*	123	0.6
Total	22,517	100.0

*Other includes blacks and whites of unknown ethnicity.

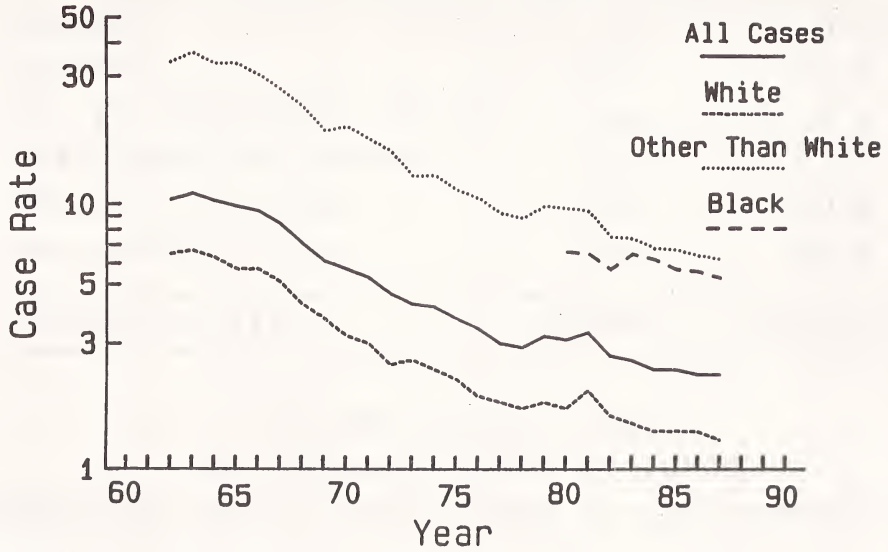
Tuberculosis Case Rates
And Relative Risk By Race and Ethnicity
United States, 1987

Race/Ethnicity	Case Rate*	Rate Ratio
Non-Hispanic White	4.3**	1.0
Asian/Pacific Islander	48.1**	11.2
Non-Hispanic Black	27.6	6.4
American Indian/ Alaskan Native	20.0**	4.7
Hispanic	18.7**	4.3

*Rate per 100,000 population.
**Rates based on 1985 population estimate.


Reported Tuberculosis Cases
Children Under 15 Years
United States, 1962-1987
Cases
7000
6000
5000
4000
3000
2000
1000
0
60
65
70
75
80
85
90
Year

Reported Tuberculosis Case Rates* In Children Under 15 Years Of Age, By Race, United States, 1962-1987



*Rate per 100,000 population.

Reported Tuberculosis Cases By Race/Ethnicity
In Children Under 15 Years
United States, 1987

Race/Ethnicity	Cases	Percent
Non-Hispanic White	224	19.0
Non-Hispanic Black	421	35.8
Asian/Pacific Islander	172	14.6
Am. Indian/Alaskan Native	34	2.9
Hispanic	321	27.3
Unknown	5	0.4
Total	1,177	100.0

Mr. WAXMAN. Thank you all for your testimony.

Dr. Comstock and Dr. Banton, both of you have been directly involved with CDC's Advisory Committee for the Elimination of Tuberculosis. Would the two of you please explain the various functions of this committee and give us a brief description of the work it has done since 1987?

Mr. BANTON. Well, since the committee was established in 1987 there has been tremendous input into the plan. There have been literally thousands of experts and scientists from all over the country who have commented on the plan.

Part of the beauty of the plan is that it has been very open and realistic from the standpoint of dealing with realistic situations, and in recognizing the obstacles that are in its path and so forth.

Mr. WAXMAN. Give us a description of the plan, of the work of the committee itself.

Mr. BANTON. The committee so far has made several recommendations in regard to approaches in high-risk populations such as specific detailed recommendations for the control of tuberculosis in, for instance, prisons and in the control of tuberculosis in HIV populations. It made recommendations that will be coming out regarding the control of tuberculosis in nursing home situations. So they made recommendations to help various high-risk groups in bringing about TB control.

Mr. WAXMAN. Dr. Comstock, are you urging this committee be made permanent?

Mr. COMSTOCK. I would think it would be very useful to the whole Elimination Program to have such a committee made permanent, both to continue what it has been doing, which as Dr. Banton mentioned has been issuing rather specific guidelines for particular parts of the Tuberculosis Control Program, and also to oversee the project and to be a stimulus and maybe even a gadfly now and again.

Mr. WAXMAN. Let me ask you, since you are all physicians with an expertise in TB, can you give us the costs of treating a TB case? How expensive might it be? Do many untreated TB patients end up in the hospital?

Mr. REICHMAN. Well, the cost of treating a tuberculosis case may be as cheap as just getting a person to take medication and the cost of the medication, which might be a dollar a day.

When you add the fact that most patients do not like to take medication—and we know that even healthy physicians or Congressman tend to take their medication maybe half of what they are prescribed—you add the importance that was discussed earlier by Dr. Hinman and Dr. Snider about directly administered therapy, where the patient has to come into your clinical setting or you better send a health aide, a person from the community out to administer the therapy in the home, then you are increasing the cost. But the cost is your first pass. You can cure any first case of tuberculosis in 6 months.

If the person is lost to followup, doesn't take his medication, then that individual is going to develop resistant tuberculosis. He is going to infect his close associates and family members with resistant tuberculosis, which may have to be treated with more toxic, more expensive drugs for a longer period of time.

So to sum up, it is cheap in the first pass. It is much more expensive and extends the health care system monumentally if you have to do it over and over again.

Mr. WAXMAN. The organizations that you represent have endorsed the HHS TB Elimination Plan and have committed themselves to achieving this goal. What types of TB services and programs will your organization support in response to this initiative? How do they work with the CDC TB program itself?

Mr. COMSTOCK. With respect to the American Thoracic Society, that has been the organization in the past that has put forward the authoritative statements as to how to handle specific problems. With the advent of the Advisory Committee, we have been able to operate somewhat more rapidly than that organization did, but we have been able to work in cooperation with them so that we are getting their input as well as our input.

So as far as professional education is concerned, the American Thoracic Society and the Advisory Committee have worked closely together. The Lung Association, I am not quite so closely associated with that.

Mr. REICHMAN. The American Lung Association, the national American Lung Association is made of affiliated associations in every State and several smaller areas. These associations historically have been advocates for tuberculosis care, control and prevention. These have been mobilized by the American Lung Association to do exactly what the American Lung Association and Thoracic Society have been doing on a national level on a State and local level. So as soon as the plan came out, all of the local lung associations were involved in having the plan and organizing tuberculosis control activities and consciousness raising in both the government and private sectors in their various constituencies.

Mr. BANTON. I would say similar activities are in the process of going on with the American Public Health Association. In terms of education of the public, APHA is building the level of awareness that tuberculosis is still an important public health problem. Also the affiliates or the chapters of the American Public Health Association, like the Missouri Public Health Association, have made important contributions. Missouri is the one State that has taken the national plan and tailored the national plan to the resources and needs of the State. So the Missouri Public Health Association has been a tremendous help in that regard.

Mr. WAXMAN. Over the past year, the Public Health Service has recommended that TB patients be counseled and tested for AIDS and that HIV-positive persons be given diagnostic tests and early interjection drugs. The PHS has said that is a "state-of-the-art" medicine and public health.

Have TB clinics gotten money to go along with these recommendations? Can you stretch your funds to continue with your original TB control efforts while carrying on these AIDS control programs as well?

Mr. COMSTOCK. Well, speaking from a small local health department, we are able to do that. Our major problem over the past 10 years with the TB funds is that they have been cut, and cut, and cut which means that we have to limit our activities to a more and more high-risk groups, which means other groups are let go.

I think in a small county like ours, we are still able to do what should be done with tuberculosis and AIDS. We are hoping that we can do more.

That depends on further funds both locally and from the State and, I guess, eventually from CDC to some extent. That is a very small health department that I happen to know about.

Mr. REICHMAN. I am speaking for a larger health department that has a huge tuberculosis rate—I believe it hasn't been released yet, but Newark's tuberculosis rate has risen precipitously over the past year to where I think we will be No. 1 or 2 in the country—where we have a huge problem with coinfection with tuberculosis and HIV infection.

Because we are providing basic services to the tuberculosis patients and their contacts, we have to raise the amount of preventive therapy we are giving. Preventive therapy of people who have both infections is extremely cost effective. It prevents tuberculosis from occurring in these individuals.

But these are individuals who are asymptomatic. They do not feel any illness. It is hard to get them to take their medicine.

So one thing we should be doing and haven't been able to do is to extend directly administered therapy to a person who is at extraordinarily high risk of getting TB. We give lots of preventive therapy to our TB cases, but we cannot yet afford to give preventive, directly administered preventive therapy to people who are at high risk of becoming TB cases.

Mr. BANTON. We have the same problems in Kansas City and in the State of Missouri. Limited resources. It is very difficult to do even though people are committed.

We call on persons in allied programs, the immunization programs, to help us out but this is sporadic depending upon the needs of the other program at that point in time. We are resource limited tremendously, mainly because the level of awareness of the importance of tuberculosis has gone down so because of the precipitous drop in the number of TB cases.

There are so many people now who feel that the tuberculosis problem is no longer a problem. So we have to spend a great deal of time in raising the level of awareness that TB is still with us. Many people are shocked to hear that the tuberculosis infection is—still infects about half of the world's population.

Mr. WAXMAN. Mr. Nielson.

Thank you, Mr. Chairman.

The Chairman, has asked every question but one that I have.

Let me ask the one that he has not asked.

Dr. Reichman, you have suggested that statutorily we should establish the Commission for the Advisory Committee for the Prevention of Tuberculosis into a statute.

Mr. REICHMAN. Yes.

Mr. NIELSON. Shouldn't the—could that committee still function without a statutory requirement?

Mr. REICHMAN. Yes, it still could function without the statutory requirement as it has. But the committee would then, I guess, rest on the interest in the Secretary of Health and Human Services and the hierarchy in the Centers for Disease Control. And, as you know, public health priorities sometimes wax and wane. As they

get on to other interests, they may forget about the Advisory Committee for the Elimination of Tuberculosis.

Mr. NIELSON. Do you think Dr. Comstock's comment or Mr. Banton's comment who said we have to have more priorities for it?

People have the perception that it is gone? Do you think that would help if it were satisfactorily mandated?

Mr. REICHMAN. I think it would be a very important second step. Becoming one who has always been interested since Dr. Comstock was my teacher in tuberculosis and being on the front lines of tuberculosis control, I know it is very hard to raise the consciousness of other individuals.

I think having the Advisory Committee, and having your committee with its previous interest and involvement in tuberculosis control have gone to some way in getting this accomplished.

But still when I go to my own State legislature or go to individuals in my own local government, they say, "TB"? We didn't know there was still "TB". That has brought TB back into the public eye. I think making the statutory commitment for the committee to exist will continue to do that.

Mr. NIELSON. Now some things about the legislation itself. The bill calls for authorizing $36 million as has been the case.

Congress has appropriated $6 million. How do you account between the $36 million authorized and the $8 million appropriated? Did you put enough pressure on them? How do you account for not putting pressure on the Appropriations Committee?

The authorization commission did very well by you. How come that translates into less than a quarter of it?

Mr. REICHMAN. I had the privilege of testifying at the House Appropriations Committee.

Others from the American Lung Association and American Thoracic Society, I believe, testified on the Senate side.

Mr. NIELSON. But you only got 23 cents on the dollar.

Mr. REICHMAN. Unfortunately, the administration prior to Secretary Sullivan becoming involved, as I understand their budget, had nothing for tuberculosis control. They wanted to leave it for the States. But in our testimony we pointed out that tuberculosis is the disease that does not follow State lines and a national effort is required. So we got a little bit on the dollar.

Hopefully, with the continued consciousness raising and information that comes not only from our society but the American Public Health Association——

Mr. NIELSON. You didn't convince the majority party in the House either, because 23 cents on the dollar is not very good return, usually. Anyone else like to comment on that?

Mr. COMSTOCK. A major problem I think you put your finger on and Dr. Reichman recognizes is the perception is that tuberculosis is no longer a problem. I think anything we can do to combat that will help the Elimination Plan. And if the Congress in its wisdom sees fit to make the Advisory Committee a continuing official organization it sends a powerful message that we still have a problem and will continue to have a problem until we do something about it.

Mr. NIELSON. It is with the whole Appropriations Committee.

Mr. COMSTOCK. The whole country, I hope.

Mr. NIELSON. Let me ask two other questions.

Dr. Hinman suggested there will be a 5-year appropriations, a 5-year authorization, I should say. The bill proposes a 3-year authorization.

Do you have any strong feelings either way whether it should be a 5-year authorization or a 3-year authorization, any of you?

Mr. BANTON. Certainly the longer the better. After all, the plan calls for, if all of the societal components are committed and work hard on the plan, we will have elimination by the year 2010.

I certainly don't know anything about the authorization and appropriations process but I would certainly recommend the five.

Mr. NIELSON. Now anyone else want to comment? The other question is you changed the language in the bill from prevention and control to prevention, control and elimination. That is a committee. By a stroke of the pen—does that guarantee it is going to happen?

Mr. COMSTOCK. No, but it is the first step, isn't it?

Mr. NIELSON. It is optimistic. Adds the word elimination, does that mean it is about to go away or not?

Mr. BANTON. We are not even going to say it will go away. Elimination by the World Health Association is one case per million. Eradication is like small pox which is the only one that we have really——

Mr. NIELSON. You don't worry that the words and elimination—5 years goes by and it hasn't been eliminated, don't you think Congress will say, look, we tried, you haven't eliminated it, why should we reauthorize it? I am posing a worse-case scenario?

Mr. COMSTOCK. I am hoping that the people would have looked at the plan and realized that it was a 20-year plan and not a 5-year plan. I will be very surprised.

It takes time to get these things going. It takes time to get the new research started. It takes time. I would hope that it would be—I like the bill. I think we need to spend more time with the Appropriations Committee.

Mr. NIELSON. Maybe you can eliminate it and cut it down to the one in a million that you mentioned.

I commend all three of you for the work you have done and appreciate the Chairman for having this hearing.

Mr. WAXMAN. Thank you very much, Mr. Nielson.

Gentlemen, we appreciate your contribution to this hearing and we look forward to working with you on this whole matter.

With that, it concludes our business for today and we stand adjourned.

[Whereupon, at 10:45 a.m., the committee adjourned.]

PUBLIC HEALTH PROGRAMS

Childhood Immunization Program Reauthorization

WEDNESDAY, MARCH 7, 1990

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:10 a.m., in room 2218, Rayburn House Office Building, Hon. Henry A. Waxman (chairman) presiding.

Mr. WAXMAN. The subcommittee will come to order.

Today's hearing is on the reauthorization of the Childhood Immunizations Program.

This is an effort that has the nominal support of everyone who discusses it. No one is opposed to polio vaccine. No one is opposed to county health nurses delivering shots. No one wants a return of childhood epidemics of infectious disease.

The problem is not political controversy. The problem is dollars.

For years, the Reagan administration sent the Congress budget requests that did not keep up with the inflation in vaccine costs, that eliminated the States' ability to manage programs, and that assumed away increases in need among poor children. And for years the Congress rejected those budgets as shortsighted and unworthy of debate.

We had hoped that this year's budget from the Bush administration would be more pragmatic, and in many ways it is. The administration does not ask for the program to be ended, to be scaled back, or to shift its responsibilities.

But the administration proposal still has one glaring failure—measles.

In 1983 there were about 1,500 cases of measles in the United States. In 1989 there were more than 10 times that number.

As a result of these outbreaks, last fall the CDC and the American Academy of Pediatrics reviewed current immunization practices. The final CDC recommendation is that children get a second measles shot. Some experts argue for all children to do so. CDC compromised and said that at least those children entering first grade and those students entering college should.

But despite these recommendations, the President's budget includes no money for these shots. Despite the best advice of its own epidemiologists and researchers, the Bush administration has lowered our guard against infectious disease in children.

Measles isn't the only problem; it's just the biggest. There are also shortfalls in hepatitis vaccines for newborns, in State operating expenses, and in the stockpile of vaccines for emergency shortages.

I don't know why childhood immunizations remains a budget issue. The dollars are small, and research has shown that we save as much as $90 for every dollar spent.

But I do know that we can't try to save pennies here. We cannot allow children to die of diseases that should never occur and we cannot afford to treat children for crippling conditions that we can prevent.

With today's hearings I hope that we can move forward to providing adequate funding for the Childhood Immunizations Program and move beyond debating this essential service in every budget year.

Before I call on our first witness at today's hearing, Dr. Alan R. Hinman, I want to recognize Dr. Roy Rowland, a very distinguished and important member of this subcommittee who I am delighted to have with us today.

Mr. ROWLAND. Thank you, Mr. Chairman.

I don't know why it's a budget problem either. It is almost unbelievable that it would be a budget problem. I guess when someone says childhood diseases they almost think about benign childhood diseases. Measles is not a benign disease at all, as you well know, nor any of the other childhood diseases.

The immunization programs save so much. Not only in human suffering, but the monetary savings, because of the immunization programs that we have had in place for a half a century now and have continued to improve on over the years.

I don't think it ought to be a budget problem at all. I think it is so very important. We need to be sure that it is fully funded in every instance.

I thank you very much, Mr. Chairman.

Mr. WAXMAN. Thank you, Dr. Rowland.

Mr. Nielson.

Mr. NIELSON. No opening statement.

Mr. WAXMAN. Let me ask unanimous consent that we keep the record open for opening statements that members may wish to insert.

[The prepared statement of Hon. John D. Dingell follows:]

PREPARED STATEMENT OF HON. JOHN D. DINGELL

Immunization against infectious disease is one of the most successful prevention programs in public health. It is not only cost effective, but one sure way to guarantee the future health of our Nation's youngest citizens.

But the United States in failing to ensure that all of our children are vaccinated. Too many children are not reached until they get to school age or later, and by then it is often too late. Federal leadership is needed to ensure that all infants and children are reached.

Vaccination of individuals alone does not work to prevent disease. In order to protect public health, we need to achieve and maintain a high level of immunization throughout the population to prevent outbreaks of the vaccine-preventable diseases. What happens when this is not the case has recently been dramatically demonstrated in Michigan with an outbreak of measles.

I am disappointed that the President's fiscal year 1991 budget has failed to recognize the importance of childhood vaccinations and has ignored the Public Health

Service recommendations for second measles shots. This reflects poorly on the administration's health priorities, and undermines the ability of the United States to be an effective leader in worldwide vaccination efforts.

I congratulate Chairman Waxman on bringing forward the reauthorization of the Childhood Vaccination Program. This legislation addresses the need for increased funding for the program in general, and specifically for countering measle outbreaks.

I am also pleased that this legislation can serve as a vehicle for the reauthorization of the National Vaccine Program. I was the original sponsor of this program when it was first developed as subtitle I of the National Childhood Vaccine Injury Act (Public Law 99-660). This program has the important aim of focusing and directing the development of new vaccines.

I am pleased to join with my colleagues, Mr. Madigan and Dr. Rowland, in cosponsoring and supporting this legislation.

Mr. WAXMAN. Our first witness at today's hearing is Dr. Alan R. Hinman, who is director of the Center for Prevention Services at the Centers for Disease Control. CDC is the Federal Agency which administers the Childhood Immunizations Program.

Dr. Hinman, we are pleased to have you with us this morning. Your prepared statement will be in the record in full. We would ask you to limit your oral presentation to no more than 5 minutes.

STATEMENT OF ALAN R. HINMAN, DIRECTOR, CENTER FOR PREVENTION SERVICES, CENTERS FOR DISEASE CONTROL, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY WALTER ORENSTEIN, DIRECTOR, DIVISION OF IMMUNIZATION

Mr. HINMAN. Thank you very much, Mr. Chairman.

I am Alan Hinman. I am director of the Center for Prevention Services at CDC. I am accompanied by Dr. Walter Orenstein, who is director of the Division of Immunization at CDC.

I am pleased to appear before the subcommittee to discuss reauthorization of the Immunization Grant Programs.

Since its establishment by the Vaccination Assistance Act of 1962, CDC's Immunization Program has become one of the most successful prevention programs in public health. Immunization levels at school entry for measles, rubella, polio, diphtheria, tetanus and pertussis have been 95 percent or greater since the 1980-81 school year.

These high immunization levels have led to reductions of 90 percent or more in each of the vaccine-preventable diseases.

The effectiveness of this program is attributable to a collaborative, vital partnership between official health agencies and the private sector at the national, State and local levels. At present approximately 50 percent of America's children receive their vaccines in the public sector. In 1989, CDC's Immunization Grant Program supported the purchase of approximately one-half of these doses of vaccine or about 25 percent of the national total.

Successful immunization programs require more than vaccine alone. Intense surveillance of disease, comprehensive management, promotion of programs, monitoring of adverse events following immunization, evaluation and assessment of immunization levels are all essential. All of these activities are personnel intensive and our Immunization Program provides critical support for State program operations to hire and maintain the required staff.

Since our last hearing in 1987, CDC's Immunization Program has undertaken new efforts to reduce the burden of several infectious diseases. In 1987 conjugated *Haemophilus influenzae* type B vaccines were licensed to prevent bacterial meningitis in children and were recommended for all children at 18 months of age.

The President's 1991 budget request will enable CDC to provide $12.1 million to assist State purchase of this vaccine. The potential for reducing the burden caused by bacterial meningitis should increase in the future when conjugated vaccines become licensed for use in infants younger than 18 months who actually have the highest risk of acquiring this disease.

Hepatitis B infection is a serious problem in some infants and children. The fiscal year 1991 budget request contains almost $8 million to help break the cycle of mother-to-infant transmission. The funds in the grant will support screening of pregnant women to detect carriers of hepatitis B, and the administration of vaccine and hepatitis B immune globulin to infants born to women who are infected.

CDC's Immunization Program faces a number of challenges as it moves into the 1990's. Foremost among them is maintaining provision of adequate numbers of vaccine doses given the record of skyrocketing vaccine costs in the past. There is a table in the testimony that demonstrates this.

We hope that the Compensation Program established through the National Childhood Vaccine Injury Act of 1986 will help continue the recent stabilization of prices by decreasing manufacturer liability.

Despite instability over the last several years in vaccine prices, appropriated grant funds have remained sufficient to purchase the same number of doses of vaccines from 1987 to 1990. The President's 1991 budget request contains $130.8 million to continue the Grant Program at this level.

Another challenge for the 1990's is the recent resurgence of measles. In 1989, as you have mentioned, we had more than 16,000 cases, the largest total since 1978, and more than 40 measles-associated deaths in this country, the largest number since 1971.

We have learned much about measles and it has been occurring recently in two major groups—preschool children and school-aged children and young adults. The preschool problem involves innercity unvaccinated children.

School and college-age outbreaks basically are problems of vaccine failure, cases occurring in the 2 to 5 percent of individuals who received vaccine but who are not protected.

These two problems require substantially different solutions. We need to improve preschool vaccine coverage in the innercities.

To accomplish this or to give us guidance, we have begun an Infant Immunization Initiative. The 1991 budget request includes nearly $7.9 million in program operations to continue activities initiated in 1990 to improve our capacity to deliver vaccines at the appropriate age, particularly to the hard-to-reach populations in large, innercity areas.

Measles among school and college aged individuals requires a different solution—revaccination. Our Advisory Committee on Immunization Practices has recently recommended two approaches for

this: (1) aggressive revaccination during outbreaks in schools and colleges, and (2) initiation of a universal two dose vaccination schedule.

Another challenge of the 1990's is to assure use of the safest possible vaccines in the safest possible manner. Later this year CDC and FDA will initiate the Vaccine Adverse Event Reporting System, which will unify the two current systems for collection of adverse events reports.

In the future we also can look to the licensure of new and improved vaccines which will enhance our ability to reduce the burden of infectious diseases and prevent adverse events. A vaccine to prevent chickenpox may become available in the next year or two.

Acellular pertussis vaccines are also under development.

Additionally, the Institute of Medicine recommended in 1988 that we give strong consideration to a regimen of polio vaccine which would include both the use of inactivated vaccine and oral polio vaccine.

Mr. Chairman, the U.S. Immunization Program has achieved a remarkable record of success. However, to sustain that success a continuing strong commitment on the part of the Federal Government, States and the private sector must be maintained. The administration is requesting reauthorization of the Immunization Grant Program for a period of 5 years at the level of $130.9 million for fiscal year 1991 and such sums as may be necessary for the following 4 fiscal years.

Mr. Chairman, I would be happy to answer any questions you or other members of the subcommittee may have.

[Testimony resumes on p. 65.]

[The prepared statement of Mr. Hinman follows:]

STATEMENT OF

ALAN R. HINMAN, M.D., M.P.H.
DIRECTOR, CENTER FOR PREVENTION SERVICES
CENTERS FOR DISEASE CONTROL
PUBLIC HEALTH SERVICE
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman, I am Dr. Alan Hinman, Director, Center for Prevention Services, Centers for Disease Control. I am pleased to appear before the Subcommittee to discuss reauthorization of the Immunization Grant Program (Section 317(j)(1) of the Public Health Service Act). I am accompanied by Dr. Walter Orenstein, Director of the Division of Immunization at CDC.

Since its establishment by the Vaccination Assistance Act of 1962, CDC's Immunization Program has become one of the most successful prevention programs in public health. Immunization levels at school entry for measles, rubella, polio, diphtheria, tetanus and pertussis have been 95 percent or greater since the 1980-81 school year. (Table 1) Similar levels have been achieved for mumps vaccine since 1981-82. For the last several years, coverage has ranged from 97 percent to 98 percent for all vaccines. Coverage of participants in Headstart and licensed daycare facilities is also currently 94 percent or higher. (Tables 2 and 3)

These high immunization levels have led to reductions of 90 percent or more in each of the vaccine-preventable diseases, with decreases of 98-99 percent for diphtheria, measles, pertussis, polio, rubella, and congenital rubella syndrome. (Table 4)

The success of the childhood vaccination program has resulted in considerable savings. It is estimated that approximately $1.5 billion dollars are saved annually from the prevention of polio and measles alone.

The effectiveness of the program is attributable to a collaborative, vital partnership between official health agencies and the private sector at the National, State, and local levels. At present, approximately 50 percent of the childhood vaccines are administered in the public sector. In 1989, CDC's Immunization Program supported the purchase of approximately one-half of these doses or about 25 percent of the total.

Successful immunization programs require more than vaccine alone. Intense surveillance of disease is also necessary along with emergency outbreak control measures when disease is detected. Comprehensive management is needed to assure vaccine supplies are adequate and that vaccine is shipped and stored appropriately. In addition, vaccination as a primary preventive measure must be promoted both to providers and potential recipients with targeting of those efforts to the populations most in need. Monitoring of adverse events following vaccination, ensuring adherence to appropriate precautions, and assessing risk factors for adverse events are also critical to the assurance of vaccine safety and the maintainance of public confidence in the Program. Finally, individual programs must be carefully evaluated, including assessment of immunization levels, to ensure that problems are found and solved. All these activities are personnel-intensive and our Immunization Program provides critical support for State program operations to hire and maintain the required staff.

Since 1987, CDC's Immunization Program has undertaken new efforts to reduce the burden of several infectious diseases. In that year, conjugated Haemophilus influenzae type b vaccines (HbCV) were licensed

and recommended for all children at 18 months of age. The FY 1991 budget will enable CDC to provide $12.1 million to assist state purchase of this vaccine. Invasive infections caused by Haemophilus influenzae type b result in an estimated 20,000 cases of meningitis, pneumonia, cellulitis, arthritis, septicemia, epiglottitis, and a variety of other serious illnesses that lead to approximately 1000 deaths annually. This disease burden is similar in magnitude to that of paralytic poliomyelitis prior to the availability of vaccines. Under present recommendations, HbCV can potentially prevent only one-third of these serious illnesses because the bulk of cases occur in children younger than 18 months. The potential for reducing this terrible burden should increase in the future when conjugated vaccines become licensed for use in infants younger than 18 months.

Hepatitis B causes an estimated 300,000 new infections annually leading to an estimated 4,000 (future) deaths from cirrhosis and 800 (future) deaths from liver cancer. Chronic complications of hepatitis B are particularly likely if infection is acquired in the perinatal period. An estimated 18,000 infants are born annually to chronically infected mothers; approximately 4,000 of these infants are also chronically infected. More than 25 percent of these individuals will die from cirrhosis or cancer. The FY 1991 budget contains almost $8.0 million to help break this cycle of mother-to-infant transmission. These funds will support the universal screening of pregnant women to detect carriers and the administration of vaccine and hepatitis B immune globulin to infants of carrier mothers. This represents a major step to eliminate hepatitis B as a significant health problem in the United States. Further

information is now being collected to better define how to prevent hepatitis B in other high-risk populations, including all infants born to Pacific Islanders and foreign-born Asian women as well as individuals who acquire disease through heterosexual contact.

CDC's Immunization Program faces a number of challenges as it moves into the 90's. Foremost among them is maintaining provision of adequate numbers of vaccine doses given the record of skyrocketing vaccine costs in the past. Figure 1 shows the costs of diphtheria, tetanus toxoids, and pertussis vaccine (DTP) in the public sector from 1980 through 1989. Prices increased from about $0.15 per dose in 1982 to a peak of $9.62 in 1988. This was associated with a marked increase in law suits filed against manufacturers which reached a high of 255 suits in 1986. It is hoped that the Compensation Program established through the National Childhood Vaccine Injury Act of 1986 will help continue the stabilization of prices by decreasing manufacturer liability.

DTP vaccine prices are now similar to prices in 1987 despite the addition of $4.56 excise tax per dose on all vaccines sold since 1988. Law suits filed against manufacturers have decreased steadily since 1986; 114 suits were filed in 1988. While prices for measles, mumps, and rubella (MMR) vaccine and oral polio vaccine (OPV) increased substantially because of the imposition of excise taxes in 1988, MMR prices remained stable through 1989 and have dropped by $1.47 in 1990. (Table 5) The price for HbCV decreased from $11.00 per dose in 1988 when there was only a single manufacturer to $6.00 per dose in 1989 when a second manufacturer was

licensed. Despite the instability in vaccine prices, appropriated grant funds have remained sufficient to purchase the same number of doses of vaccines from 1987 to 1990. The FY 1991 budget request contains $130,862,000 to continue the grant program at this level.

A second major challenge is the recent resurgence of measles. While the current incidence is only a fraction of the occurrence during the prevaccine era, the disease has not been eliminated. Although an average of only 3,000 cases was reported annually from 1981 through 1988, the number of cases increased to more than 16,000 in 1989, the largest total since 1978. (Figure 2) More than 40 measles-associated deaths were reported in 1989, the largest total since 1971.

We have learned much about measles over the past decade and recognize that it occurs in two major groups: preschool- and school-aged children. (Table 6) The preschool problem primarily involves inner-city populations of unvaccinated children, many of whom are younger than 15 months, the routinely recommended age for vaccination. Most of the serious complications have been associated with these outbreaks. Of the 45 deaths reported during 1989, 30 occurred among preschool children.

In contrast, the problem in school- and college-aged populations appears to be one of vaccine failure. A majority of cases in these outbreaks occur in persons who are identifiable as vaccine recipients. Because the measles virus is so contagious, transmission can be sustained in the 2-5 percent of persons who are not adequately protected by a single dose.

The two problems require substantially different solutions. Measles among inner-city populations is symptomatic of underlying problems in overall vaccine delivery to these socioeconomically disadvantaged groups. While vaccination levels are high among children entering school in these populations, many of the younger children are not vaccinated at the recommended age necessary to protect them against diseases such as measles. Recognizing the need for earlier, age-appropriate vaccination, the Immunization Practices Advisory Committee (ACIP) recently recommended that the age for the first dose of MMR be lowered from 15 months to 12 months in these populations. Implementation of this recommendation will not be easy. Experience to date suggests that immunization is not a high priority for many inner-city residents even in the presence of outbreaks, special control clinics, and intense publicity. Current immunization grant guidelines are being revised to assure that grantees focus particular attention on inner-city populations.

To improve coverage among preschool populations, we have begun an Infant Immunization Initiative. The FY 1991 budget request includes $7,881,000 in program operations to continue activities initiated in 1990 to improve our Nation's capacity to deliver vaccines at the appropriate age, particularly to hard-to-reach populations in large inner-city areas. The major goals of this initiative are to define the magnitude of the problem by developing assessment techniques to measure coverage at both the National and local level, and to learn the most cost-effective methods to achieve and maintain high age-appropriate immunization levels. Much of the early effort will be directed toward operational research of measurement and intervention approaches.

Measles among school- and college-aged individuals requires a different solution -- revaccination. Revaccination is needed because of the extreme infectiousness of measles, with transmission occurring among the 2-5 percent of persons who fail to develop antibodies following their first dose of vaccine. Recognizing this and to prevent measles transmission, the ACIP issued recommendations calling for: 1) aggressive revaccination during outbreaks in schools and colleges, and 2) a universal two-dose vaccination schedule. Currently, our highest priority is revaccination during outbreaks wherein efforts are targeted to populations at greatest risk. CDC's Immunization Program has been able to assist States in implementing revaccination programs during such outbreaks.

Another challenge is assuring use of the safest possible vaccines in the safest possible manner. Monitoring systems are necessary to detect adverse events following vaccination, to determine which events are caused by vaccine, and to identify associated risk factors. In late 1990, CDC and FDA will initiate the Vaccine Adverse Event Reporting System (VAERS), which will unify their current systems for the collection of adverse events reports. Grantees will be required to participate in VAERS and provide needed information on the characteristics of the clinical syndromes following vaccination and on possible risk factors for adverse events. In addition, many persons and groups have participated in the development of information materials required by the National Childhood Vaccine Injury Act. When these materials become available, they should help assure the best use of vaccines.

New Vaccines

The licensure of new and improved vaccines will enhance our ability to reduce the burden of infectious diseases and prevent adverse events. A vaccine to prevent chickenpox may become available in the next one to two years. Information to date suggests the vaccine is more than 90 percent effective in preventing this disease and its complications. Chickenpox currently causes an estimated 3.5 million cases annually with 73 deaths. If this vaccine becomes licensed and if recommended for universal use, it would be particularly important to implement vaccination in the public as well as private sector. This would decrease the risk that unvaccinated children would become "susceptible" adults in whom severe chickenpox-associated complications are considerably more common.

Acellular pertussis vaccines which offer the promise of greater vaccine safety, without compromising efficacy, are also under development. Upon licensure, we will have to shift to these safer vaccines.

Additionally, in 1988, the Institute of Medicine recommended strong consideration of a sequential schedule of inactivated polio vaccine (IPV) followed by oral polio vaccine (OPV) once a combined preparation of DTP and IPV becomes available. This schedule should reduce the current minimal occurrence of the 8 to 10 cases of paralytic polio caused annually by OPV. This new schedule is likely to be more costly than the use of OPV alone and more complicated to implement at the local level, and careful consideration would have to be given to the benefit associated with the increased cost.

Mr. Chairman, the U.S. Immunization Program has achieved a remarkable record of success. However, to sustain that success, a strong commitment on the part of the Federal Government, States, and the private sector should be maintained. Aside from smallpox, none of the vaccine-preventable diseases has been eradicated and there is ample evidence that disease seeks out susceptible individuals in epidemics of disease. The Administration is requesting reauthorization of the Immunization Grant Program for a period of 5 years, at the level of $130.9 million for FY 1991 and such sums as may be necessary for the following 4 fiscal years.

I would be happy to answer any questions you or other members of the Subcommittee may have.

TABLE 1

Percent Immunized by Antigen
Kindergarten/1st Grade Immunization Status
1980–1988, United States

Year	Measles	Mumps	Rubella	Polio	DTP/DT
1980/81	96	92	96	95	96
1981/82	97	95	97	96	96
1982/83	97	96	97	97	96
1983/84	98	97	98	97	97
1984/85	98	97	98	97	97
1985/86	97	96	97	96	96
1986/87	97	97	97	97	97
1987/88	98	98	98	97	97
1988/89	98	98	98	97	97

TABLE 2

Percent Immunized by Antigen Headstart Immunization Status 1980–1988, United States

Year	Measles	Mumps	Rubella	Polio	DTP/DT
1980/81	94	93	94	93	92
1981/82	93	90	92	90	88
1982/83	95	94	95	91	88
1983/84	96	94	96	94	93
1984/85	95	95	95	93	94
1985/86	96	95	96	93	93
1986/87	95	95	95	92	92
1987/88	97	97	97	96	96
1988/89	97	97	97	94	94

TABLE 3

Percent Immunized by Antigen
Licensed Day Care Immunization Status
1980–1988, United States

Year	Measles	Mumps	Rubella	Polio	DTP/DT
1980/81	94	92	93	93	92
1981/82	94	92	94	93	93
1982/83	95	93	95	94	93
1983/84	95	93	95	94	94
1984/85	94	94	94	93	94
1985/86	95	94	95	94	94
1986/87	95	95	95	94	95
1987/88	95	95	94	94	94
1988/89	95	95	95	94	94

TABLE 4

Comparison of Maximum and Current Morbidity Vaccine–Preventable Diseases

	Maximum cases (Year)		1989 Prov.	Percent Change
Diphtheria	206,939	(1921)	2	–100.00
Measles	894,134	(1941)	16,236	– 98.18
Mumps*	152,209	(1968)	5,611	– 96.31
Pertussis	265,269	(1934)	3,745	– 98.59
Polio (paralytic)	21,269	(1952)	0	–100.00
Rubella+	57,686	(1969)	373	– 99.35
CRS	20,000+	(1964–5)	3	– 99.99
Tetanus§	601	(1948)	47	– 92.18

*First reportable in 1968
+First reportable in 1966
§First reportable in 1947

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TABLE 5

Federal Contract Prices of DTP, MMR, OPV and HbCV 1980–1990

Year	DTP	OPV	MMR	HbCV
1980	$ 0.15	$ 0.354	$ 2.71	NA
1981	0.15	0.396	3.12	NA
1982	0.15	0.475	4.02	NA
1983	0.42	0.582	4.70	NA
1984	0.65	0.728	5.40	NA
1985	2.21	0.804	6.85	NA
1986	3.01	1.56	8.47	NA
1987	7.693	1.363	10.67	NA
1988	8.456	1.363	16.18	11.00
1989	7.961	1.92	16.18	6.00
1990	7.961	1.92	14.713	6.00

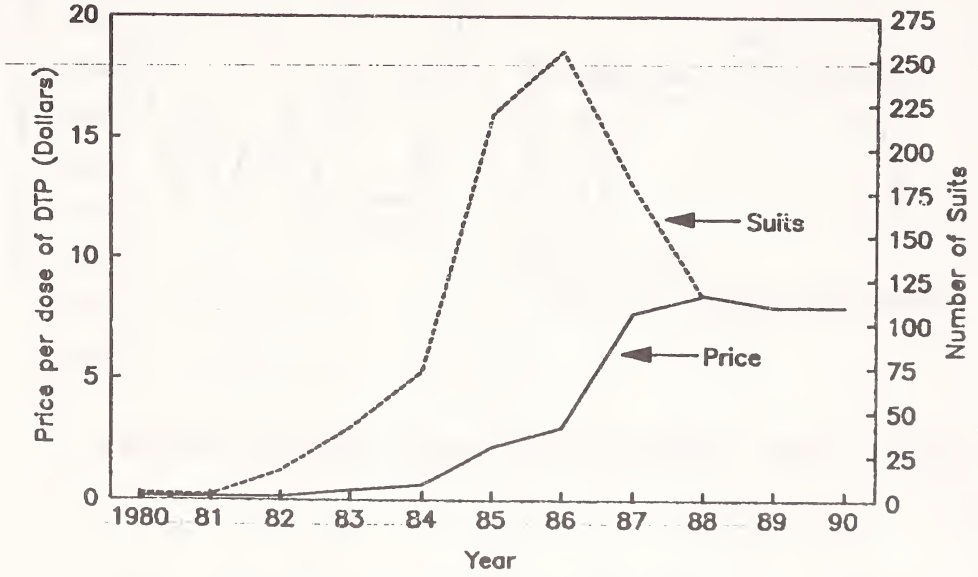
TABLE 6

Measles Outbreaks in the United States 1985 and 1986

	Patterns of Measles Transmission	
Variable	Preschool	School
Areas	Inner cities	All
Patient		
Vaccination	Mostly unvaccinated	Mostly vaccinated
Age <16 mo	~ 1/3 of cases	<5% of cases

FIGURE 1

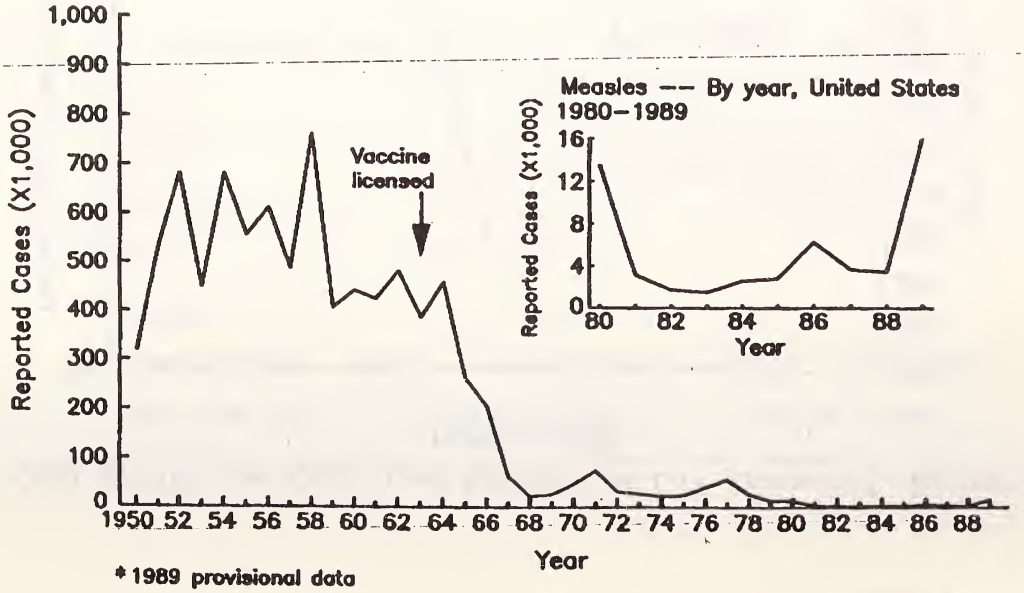
Cost of DTP per Dose and Number of DTP Lawsuits*, by year 1980–1990



*Data for lawsuits not available for 1989–1990.

FIGURE 2

Reported Measles Cases, United States, 1950–1989*



* 1989 provisional data

Mr. WAXMAN. Thank you very much, Dr. Hinman.

As you note in your testimony, there is a medical consensus now—which includes the administration's own experts—that every child should have two measles shots, not just one. The President's budget has no money for this expanded measles immunization recommendation.

My question to you is, why not?

Mr. HINMAN. The President's budget, as you note, requests funds to support the continuation of activities as well as the continuation of measles outbreak control. It does not contain funds to support a second measles vaccine as a routine.

Mr. WAXMAN. I know it doesn't. I am asking you why it doesn't.

Mr. HINMAN. There are probably a variety of reasons, including the fact that the recommendation of the Advisory Committee was not published officially until after the budget request was prepared.

Mr. WAXMAN. If we were to implement the recommendation from CDC of the second dose of measles vaccine, how much would it cost?

Mr. HINMAN. We estimate that there are about 4 million children born each year in the United States. There are another 2.4 million adolescents and young adults entering college. This means that implementation of the ACIP's recommendation would involve about 6.4 million doses of measles vaccine. If the public sector provided half of that vaccine, the public sector cost would be approximately $48 million.

Mr. WAXMAN. As you know, the American Academy of Pediatrics does not believe that the CDC recommendation of a second measles shot is adequate. They argue, and it makes a lot of sense, that if you only vaccinate children entering first grade and those entering college, then the children in grades 2 through 12 have a long time to wait. Why do the CDC and the ACIP limit themselves to these two points of access? Was it entirely a budget decision?

Mr. HINMAN. I think there were a number of factors, including budgetary. I think also there are some delivery problems as well as production issues. A massive Vaccination Program which would seek to vaccinate in 1 year, for example, all children ages 18 months to college age would involve a tremendous amount of vaccine, a very great increase in the number of visits to health care providers, and would, I think, be administratively very, very difficult to accomplish.

Mr. WAXMAN. In addition to that second measles shot, we would also need additional funds for those areas that are experiencing measles outbreaks. How much would that cost?

Mr. HINMAN. Our budget request this year provides nearly $10 million to support measles outbreak control activities.

Mr. WAXMAN. In my own State of California there have been severe problems with measles. Recently, when one group tried to carry on a Public Vaccine Program they were told that there wasn't enough vaccine to go around. Is there a shortage of Federal funding for vaccine for outbreak areas? How much do we really need to deal with the measles control?

Mr. HINMAN. As I mentioned, the request includes approximately $10 million to support measles outbreak control.

Mr. WAXMAN. Do you think that will deal with these hard hit areas as well?

Mr. HINMAN. It will provide some assistance to them. Whether it will provide all of the assistance they feel they need is subject to question.

Mr. WAXMAN. In your professional judgment, can you tell us what dollar figures you think are going to really be needed to deal with this measles outbreak control, especially as we look at some of these severe outbreak areas? I have heard of a need for closer to $20 million. In your personal judgment, not as a representative of the administration's official position—which figure do you think is the most accurate in terms of the need?

Mr. HINMAN. Our assessment based on requests that we have received from States and their description of activities is that this might entail something on the order of $22 million or $23 million.

Mr. WAXMAN. That is what they are telling you they are going to need?

Mr. HINMAN. That's correct.

Mr. WAXMAN. In addition to the purchase of vaccines, the Immunization Program provides money for State program costs. Can you tell us what the money is used for?

Mr. HINMAN. The current request includes approximately $19 million to support State program operations. This provides support for the surveillance of disease, the coordination of programs, investigation of outbreaks, the assessment of immunization levels, and monitoring programs for adverse events. The type of activity which we feel is critical.

Mr. WAXMAN. How much does the President's budget propose for those activities?

Mr. HINMAN. Approximately $19 million.

Mr. WAXMAN. When we had our hearings on measles in California, the State and local officials said that they had requested assistance from the Federal Government in just these sorts of efforts and had been told that all the money had been allocated. Are other States requesting assistance that cannot be provided?

Mr. HINMAN. Comparing the applications for awards for immunization grants to what is available, the applications we received requested in total something on the order of $30 million in support for State program operations.

Mr. WAXMAN. If we were to provide States with funds for the second measles shot, wouldn't that money also need to be accompanied by increased operation funds? Won't the measles immunization effort require more State programs to reach inadequately immunized children?

Mr. HINMAN. As I mentioned, one of our major problems at the moment is trying to reach particularly the unvaccinated innercity population. There is additional effort that is required to do that. Yes, sir. We are supporting with the Infant Immunization Initiative substantial efforts to try to develop the best strategies for this.

Mr. WAXMAN. That would involve more funds for operational costs, wouldn't it?

Mr. HINMAN. It could.

Mr. WAXMAN. In its report to the Congress, CDC said that the Hepatitis Program for mothers and children would prevent disease

and death of newborns, lower long-term liver disease problems, and lessen the risk of liver cancer.

What is the predicted impact in terms of reductions in infant deaths and the number of hepatitis carriers in the first year?

Mr. HINMAN. I will have to provide that number for you, sir. I'm afraid I don't have it.

Mr. WAXMAN. As I recall the report, it estimated 1,000 infants deaths would be prevented and 3,500 infants would be prevented from becoming carriers. I would like you to verify that so we can have it for the record.

In that same report, CDC also said this effort would cost almost $20 million. How much does the President's budget provide for this program?

[The following response was received:]

In the first year of the hepatitis B prevention program, we estimate that more than 1 million pregnant women will be screened, 8,700 infants born to positive women will be immunized with Hepatitis B Immune Globulin and hepatitis B vaccine, and 1,700 chronically infected carrier cases will be prevented.

Although hepatitis B does not cause significant infant mortality, the program initiated in 1990 will prevent 400 to 450 hepatitis B-related deaths in future years.

Mr. HINMAN. We are providing in the current budget approximately $8 million in grant support for perinatal hepatitis B transmission prevention.

Mr. WAXMAN. Has CDC made any change in its estimate of the cost of carrying out this program?

Mr. HINMAN. Not to my knowledge.

Mr. WAXMAN. CDC's stated policy is that no one can charge for federally purchased vaccine. The CDC does allow for grantees or recipients to charge for the administration of federally purchased vaccine.

As you know, I have long feared that even minimal costs will dissuade people from bringing their children in for immunizations and that the result will be more outbreaks of preventable infectious diseases. In the last reauthorization of this program, the CDC assured this committee that you would monitor fee structures during . . . State Immunization Program reviews and site visits.

What have you found?

Mr. HINMAN. Perhaps Dr. Orenstein can give a more precise answer. We do have the data. I don't have them in my mind at the moment.

Mr. ORENSTEIN. We do have data. I would like to get an answer to you that is more accurate than the one I would give off the top of my head.

[The following response was received:]

The following summarizes the responses of 52 immunization projects within the United States regarding administration fees for immunization and their impact on immunization levels.

A total of 36 (69 percent) of the responding projects indicate that at least one or more of their county health departments (CHD) and/or local public health agencies (LPHA) request a fee for administering project-supplied vaccine. Eighteen projects indicate that more than 75 percent of their CHD and/or LPHA request an administrative fee while nine projects report that less than 25 percent request an administrative fee. The remaining nine projects report that between 25 and 75 percent of their clinics request an administrative fee.

Twenty-four projects request less than $5 per visit, while 10 projects request between $5 and $10 per visit. The remaining 2 projects request between $15 and $20

per visit. In one of these projects, less than 25 percent of the clinics request a fee, while more than 75 percent of the clinics in the other project request a fee. In these projects where public clinics are not available, these higher fees are requested of public sector patients who are furnished immunization services by a private physician who receives free vaccine from the State. No charge is requested for the vaccine.

None of the 36 projects indicated that immunization services would be denied if the patient did not pay.

When asked if immunization fees contribute to lower immunization levels in the project, nine, or 17 percent of the projects responded in the affirmative.

Mr. WAXMAN. The Children's Defense Fund has suggested that the Community Health Centers are an important point for providing childhood immunizations. CHC's serve a low income population.

Are CHC's allowed to purchase vaccines at the federally negotiated price?

Mr. HINMAN. I believe so but I cannot answer the question directly.

Mr. ORENSTEIN. If it is a government agency, it would be entitled to purchase vaccine through the Federal contract for all of our vaccines.

Mr. WAXMAN. Does CDC still recommend that we maintain a 6-month supply of all routinely recommended childhood vaccines?

[The following response was received for the record:]

Also if CHC's receive Federal, State, or local public funds for vaccine, they may purchase from the Federal contracts.

Mr. HINMAN. Yes, sir.

Mr. WAXMAN. Does CDC have a full 6-month supply of each of these vaccines in the stockpile now?

Mr. HINMAN. We estimate that by the end of this fiscal year we will have approximately 90 percent of the stockpile for measles, mumps, rubella, DTP, oral polio vaccine, looking at the first dose of measles, mumps, rubella vaccine.

Mr. WAXMAN. By the end of this fiscal year?

Mr. HINMAN. That's correct.

Mr. WAXMAN. We would like to have for the record a full summary of the status of the vaccine stockpile contents.

Mr. HINMAN. Yes, sir.

[The following response was received:]

VACCINE STOCKPILE

Since the inception of the vaccine stockpile in 1983, CDC has pursued a goal of a 6-month stockpile as an emergency reserve in case the limited number of domestic vaccine manufacturers stopped production. As of October 1989, the following number of doses had been purchased: 8,434,995 doses of DTP; 7,469,600 doses of OPV; 4,500,600 doses of Td; 1,830,000 doses of MMR; 400,000 doses of DT; 19,180 doses of IPV.

The OPV stockpile is 89 percent complete; the DTP, DT, and Td stockpiles are 80 percent complete; and the IPV stockpile is 64 percent complete. The MMR stockpile is 90 percent complete for one dose; however, with the new two-dose recommendation, the current number of doses represents only 45 percent of the projected 6-month stockpile need. CDC-approval has been given five times for vaccine to be borrowed from the stockpile to prevent an interruption in the supply to the public and private sectors: once for OPV in 1984; twice for DTP in 1986 and 1988; once for Td in 1985; and once for MMR in 1986.

Between 1983 and 1990, a total of $34.6 million will have been spent on developing the stockpile. By the end of fiscal year 1990, approximately 24 weeks supply of each of the original vaccines included in the stockpile will have been purchased. This rep-

resents 92 percent of the original CDC goal for a 26-week (6-month) total stockpile supply. However, current stockpile supplies do not reflect the new ACIP recommendations for a two-dose MMR schedule, nor the inclusion of *Haemophilus influenzae* type B as a routine vaccine.

No funds are requested for the stockpile in the fiscal year 1991 President's budget. Recent vaccine compensation law should provide childhood vaccine manufacturers with greater protection from liability risks, and it is expected that additional manufacturers will enter the market. This should decrease the risk of vaccine shortages occurring. The stockpile, however, in not intended to serve as an alternative to the resolution of vaccine manufacturing liability problems. It is merely a short-term protection against production stoppages.

Mr. WAXMAN. You have been very involved with the work of the National Vaccine Program. Would you briefly describe the program's work and its plans for the future?

Mr. HINMAN. The National Vaccine Program was established by the National Childhood Vaccine Injury Act of 1986. It is charged with ensuring the optimal level of protection against disease which is preventable by vaccine and an optimal reduction in adverse events.

Our activities since inception have involved formation of a National Vaccine Advisory Committee—two of whose members will be testifying later this morning—and the formation of an interagency group which has met frequently to coordinate Federal efforts.

We have focused very heavily on intensive efforts to improve pertussis vaccines. This has entailed visits to several countries as possible sites for field trials for pertussis vaccine; consultation with manufacturers both in the United States and abroad.

We have also been involved in implementing this unified vaccine adverse events reporting system, which I mentioned briefly, and developing vaccine information materials which are called for by other provisions of the act.

We believe that it has been quite a success, I say in all modesty.

I would also, just for the record, like to note that effective March 1, Dr. Kenneth Bart became the deputy director of the National Vaccine Program, and I believe, will be able to provide it even stronger support than I have been able to on a part-time basis.

Mr. WAXMAN. I want to congratulate you on the success.

Has the plan already been completed?

Mr. HINMAN. No, sir. The vaccine plan called for in the act is being developed in conjunction with the Vaccine Advisory Committee. We have identified seven major areas, and subcommittees have addressed each of the seven. Four have been completed. We believe the last three will be completed at the meeting of the Vaccine Advisory Committee on tomorrow and the following day. They will then be incorporated into a plan which we intend to submit before the end of this calendar year.

Mr. WAXMAN. We would like you to submit the plan for the record along with the program's most recent summary of priorities and unmet needs, if you would.

Mr. HINMAN. Yes, sir.

[The following information was received:]

The National Vaccine Plan is expected to be completed by the end of the calendar year and will be submitted at that time.

The following represents the current opportunities and unmet needs related to the purposes of the NVP. The opportunities and unmet needs listed span a range of activities from basic research through program implementation. Each of the items

listed is currently being addressed by one or more agencies and represent the additional effort felt to be important.

Pertussis. The development and introduction of improved (acellular) pertussis vaccines remains the highest priority activity of the NVP. Funds appropriated to the NVP in fiscal year 1990 (approximately $4.5 million) support studies leading to a field trial of clinical efficacy of acellular vaccines as well as supporting basic and applied research. An additional field trial is planned. Thus, although the results of the research are not yet in, it appears that pertussis vaccine development is being optimally funded.

1. *Measles.* In 1989, more than 16,000 cases of measles and 43 measles-associated deaths were reported in the U.S., the highest total in more than 10 years. Advisory committees in both the private and public sectors recommended continued aggressive outbreak control measures and also recommended initiation of a routine two-dose schedule of immunization against measles (using MMR). The Immunization Practices Advisory Committee (ACIP) has recommended implementing this strategy by providing a second dose to all children entering school for the first time (approximately 4 million children) and to all students entering college for the first time (approximately 2.4 million persons). The fiscal year 1990 appropriation provided $9.9 million in additional funds to support measles outbreak control activities. It is estimated that the total public sector cost of outbreak control will require additional resources and that implementation of the two-dose schedule will add to the vaccine costs to the public sector.

In fiscal year 1990, approximately $500,000 has been allocated at CDC to support development of improved laboratory test, to support measles elimination. Additional resources could expedite development of rapid diagnostic tests and improved tests for immunity.

2. *Vaccine safety.* A nationwide unitary surveillance system for adverse events associated with vaccination (the Vaccine Adverse Events Reporting System [VAERS]) is under development and will be implemented during fiscal year 1990. In addition, CDC is allocating $1.5 million in fiscal year 1990 to expand its ability to evaluate adverse events using large linked data bases (LLDB), which allows a computerized assessment of events following vaccination and comparison with their frequency in the absence of vaccination.

A multiagency initiative is currently being developed which would include: further research to develop safer vaccines; expanded prelicensure and prerelease testing of vaccines; expanded postmarketing evaluation of vaccine manufacture, storage, distribution, and use; expanded postlicensure surveillance of adverse events; additional clinical assessment and patient care for persons experiencing adverse events; further review and research on vaccine contraindications to establish their validity and to identify risk factors for adverse events; improved communication about adverse events with health workers and the lay public; international collaboration in monitoring vaccine safety; and improved benefit-risk analyses for all vaccines. Development of this initiative is not yet complete and will require additional resources.

3. *Conjugated vaccines.* Each year approximately 20,000 U.S. children develop bacterial meningitis; a substantial proportion of these die or are left with permanent brain damage. The risk of disease and death (or complication) is greatest in infancy. Purified bacterial polysaccharides have been shown to provide protection in older children but are of little value in infancy. Recent data indicate a substantial improvement in the ability of bacterial polysaccharides to induce protection in infants if the antigens are conjugated with proteins. Conjugated vaccines for *Haemophilus influenzae* type B (Hib) have been licensed for use in 18 month to 5-year-old children and are being evaluated in infants. Conjugated vaccines for pneumococcal, meningococcal, and Group B streptococcal disease are also being developed. In fiscal year 1990, NIH will devote an additional $1.5 million to evaluate conjugated vaccines but it is estimated that this development could be significantly hastened to accelerate the introduction of these vaccines.

4. *Vaccine evaluation and regulation.* NIH currently supports six Vaccine Evaluation Units (VEU) to carry out limited clinical studies of candidate vaccines under carefully controlled conditions. These have been particularly important in assessing candidate acellular pertussis vaccines. Creation of an additional VEU would increase the capacity to evaluate candidate vaccines in an expeditious manner.

The new biotechnology/high technology-derived vaccines pose new problems for regulation, both in terms of the numbers of applications to be reviewed and in terms of the scientific skills needed to review applications and the laboratory approaches to monitor purity, potency, immunogenicity, etc. Expansion of the regula-

tory base would permit the comprehensive regulatory review to be completed in a more expeditious manner.

5. *Poliomyelitis.* Achievement of the target of poliomyelitis eradication by the year 2000 would be substantially enhanced by an expansion of technical assistance to the global effort. Concerns about the ability of existing poliovirus vaccines to achieve eradication suggest it would be important to expand efforts to develop and evaluate improved vaccine candidates.

Until eradication is achieved it will be necessary to continue poliomyelitis immunization in the U.S. To carry out the studies recommended by the Institute of Medicine to evaluate the most appropriate mix of use of inactivated poliovirus vaccine (IPV) and oral poliovirus vaccine (OPV) and to develop improved assays for determining neurovirulence and vaccine potency would cost require additional resources.

6. *Hepatitis B.* The fiscal year 1990 appropriation of $7.9 million to support hepatitis B screening of pregnant women and immunization of the newborns of those who are HBSAg carriers represents an important first step in implementing a program whose ultimate goal is to interrupt transmission of hepatitis B in this country. Full implementation of the existing recommendations, including vaccination of all infants in high risk settings (Alaska natives, residents of Pacific islands, infants of certain immigrants) would require the dedication of additional resources.

Achievement of the ultimate goal of interruption of transmission of hepatitis B will involve development and implementation of recommendations for universal immunization of infants with hepatitis B vaccine.

7. *Tuberculosis.* Tuberculosis remains a major global problem with 8 million new cases and 3 million deaths annually. The U.S. has embarked on a program to eliminate tuberculosis by the year 2010. Achievement of this goal requires the development of new diagnostic, preventive, and therapeutic tools (including vaccines), all of which are well within the scope of new technologies. In fiscal year 1990 CDC is allocating $200,000 to support TB laboratory research. To support fully the needed basic and applied research would involve additional funds.

8. *Adult immunization.* Although childhood populations in the U.S. are well immunized by the time of school entry, there are serious deficits in vaccine protection in the adult population. These deficits result both from inadequate use of existing vaccines and from suboptimal efficacy of some of them. The most serious gaps exist with regard to influenza and pneumococcal polysaccharide vaccines, for which protection in the targeted populations is generally 25 percent or less. Improvements are also needed in the protection conferred by these vaccines. Full scale implementation of a comprehensive adult immunization initiative is required. However, demonstration projects seeking to determine the most effective ways of improving immunization levels (in addition to the current demonstration projects funded by HCFA) as well as further research to improve the efficacy of influenza vaccine could be accomplished.

9. *Sexually transmitted diseases (STD).* STD continue to pose serious public health problems which are exacerbated by the fact that genital ulcer diseases (such as syphilis) may enhance transmission of human immunodeficiency virus. Among the complications of STD, pelvic inflammatory disease (PID) represents a major burden, from both economic and public health perspectives. It has been estimated that between 500,000 and 1 million episodes of PID occur in the U.S. each year; the estimated cost for PID and its sequelae is approximately $2.6 billion/year. PID is a major cause of involuntary infertility and ectopic pregnancy. Basic, immunologic, clinic, and epidemiologic studies are needed to understand the mechanisms that predispose some women to develop gonococcal or chlamydial PID, to learn the role of mucosal immunity, to identify candidate antigens for vaccines, and to develop vaccine strategies based on these findings. Additional intramural and extramural research at NIH, CDC, and FDA could hasten the development of STD vaccines.

10. *Enteric infections.* Rotavirus is the most common cause of severe diarrhea in children in the U.S., accounting for 500,000 doctor visits, 70,000 hospitalizations, and 75 to 125 deaths/year. Worldwide, 135 million cases with 870,000 deaths occur yearly. Vaccines are currently being developed and tested and are at the stage of development that clinical trials are needed to determine their safety and efficacy in the infant population. Additional laboratory studies are needed to understand patterns of protective immunity to natural rotavirus disease and to vaccines and to characterize strains and develop more effective candidate vaccines. An oral attenuated cholera vaccine (CVD103HgR) has been developed and is now ready for expanded field trials. In addition, substantial progress has also been made developing candidate vaccines for other enteric infections such as hepatitis A and shigella. Acceleration of this research would hasten introduction of new vaccines.

Mr. WAXMAN. Mr. Nielson.

Mr. NIELSON. Thank you, Mr. Chairman.

I read your testimony. How many children are actually currently vaccinated through the CDC program? Do you have an estimate for that?

Mr. HINMAN. The public sector overall, which is local and State health departments and CDC support, immunize about 50 percent of all the children in the United States. Of that, vaccine purchased with our grant funds provides about half. So we are buying through the Immunization Grant Program approximately 25 percent of all the childhood vaccines used in the United States.

Mr. NIELSON. Would you supply for the record the figures you gave Congressman Waxman on how you arrived at the $48 million? You talked about 4 million entering school and 2.4 million entering college. Would you supply that for the record?

Mr. HINMAN. Yes, sir.

[The following response was received:]

Each year in the United States approximately 4 million children enter school for the first time and approximately 2.4 million students enter college for the first time. Assuming that the private and public sectors will each continue to immunize approximately 50 percent of these students, the public sector's share would be about 3.2 million children. At the new cost of MMR vaccine ($14.71/dose), the total cost to the public sector to provide vaccine for one cohort of students would be $47.1 million. How much of that total can be borne by State and local governments is not known.

Mr. NIELSON. Only 2 to 5 percent of the people who get the first measles shot need a second one. How can you identify which ones need it and which ones don't?

Mr. HINMAN. We cannot. That is why it is recommended that all children receive two doses.

Mr. NIELSON. You recommend that but you don't ask for it in the budget. Could you revise your budget estimate to do that even at this stage?

I think the chairman had a good point. You got information after the budget was submitted but now that you know that and you now just said you recommend it, would you object if we go after it officially or otherwise?

Mr. HINMAN. The President's request does not include support for it.

Mr. NIELSON. In spite of the fact that you recommend everyone getting it even though 2 to 5 percent are the only ones that need it?

I am trying to lead you just a little bit here.

Mr. HINMAN. I gathered that.

Mr. NIELSON. As the chairman knows, I have 24 grandchildren. So I am very interested in immunizations and the problems we have there. We had a grandson who had a problem with meningitis in 1985, before you had the *Haemophilus influenza.* They recommend that be done before they are 2 years of age or 18 months. Is it safe under 18 months?

Mr. HINMAN. It is safe. The problem is that the earlier vaccines have not appeared to be effective. There is a lot of work going on.

Mr. NIELSON. A lot of them get it right at that point.

Mr. HINMAN. About 70 percent of all of the *Hemophilus B* meningitis occurs before the age of 18 months. We have been very frustrated. There are field trials under way now with conjugated vaccines looking to administer them in infancy. We are very encouraged that within the next year or two we may have it.

Mr. NIELSON. You can maybe drop it to lower than 18 months?

Mr. HINMAN. Yes, sir. Down to 2 months.

Mr. NIELSON. You talk about reauthorizing legislation. It has been suggested by some that we need $50 million for measles immunizations and $15 million for epidemic control of measles outbreak areas.

Do you support those numbers or do they seem high to you? Are those numbers completely out of line?

Mr. HINMAN. Mr. Waxman earlier asked me what the total cost of vaccine would be to provide a second dose of measles. Our estimate for the public sector providing 50 percent of vaccine needed would be on the order of $48 million.

Mr. NIELSON. So his $50 million is pretty close.

Mr. HINMAN. It is not far off.

Mr. NIELSON. What about the $15 million for the outbreak areas?

Mr. HINMAN. Mr. Waxman also asked what we had been asked by the States.

Mr. NIELSON. I know what he asked you and I know you gave him numbers. Are these numbers reasonable and are they necessary?

Mr. HINMAN. The $15 million with the $10 million that is requested is very close to the amount that the States have estimated, which is about $23 million.

Mr. NIELSON. My question again. Are they necessary?

Mr. HINMAN. Our advisory committee recommends both a second dose of measles vaccine and aggressive outbreak control.

Mr. NIELSON. Who is to pay for those? If the administration doesn't want to include them, then how do we do it? Is this another program we foist on the States without providing the wherewithal to do it?

Mr. HINMAN. Dr. Witte might wish to respond to that question from the States' perspective. We are hopeful that States will in fact provide resources for this.

Mr. NIELSON. We talked about the Vaccine Injury Act of 1986. You said it decreases manufacturers' liability. If that is the case, how long will it take for new manufacturers of vaccines to become licensed?

Mr. HINMAN. That is a very difficult question to answer. In part, there has been a reduction in the number of manufacturers recently by mergers. There have been two major mergers in the last 2 years. There are many companies working to develop, for example, pertussis vaccines. There are some 9 or 10 candidate vaccines that are currently being evaluated in NIH units.

Whether liability concerns are the things that impede manufacturers' entering the market is not entirely clear.

Mr. NIELSON. If in fact we can get some more manufacturers involved, should that lower the price of vaccines and perhaps make it easier to take care of the people with the same funds.

Mr. HINMAN. It has been our experience generally that having more than one manufacturer in the marketplace does lead to a decrease in prices.

Mr. NIELSON. So you can immunize more people with the same dollars?

Mr. HINMAN. Yes, sir.

Mr. NIELSON. Let me ask a couple of questions about hepatitis B.

What would be the impact in terms of reduction of infant deaths and the number of hepatitis B carriers in the first year of your new Prevention Program?

Mr. HINMAN. I will have to provide you that number.

[The following response was received:]

In the first year of the hepatitis B prevention program, we estimate that more than 1 million pregnant women will be screened, 8,700 infants born to positive women will be immunized with Hepatitis B Immune Globulin and hepatitis B vaccine, and 1,700 chronically infected carrier cases will be prevented.

Although hepatitis B does not cause significant infant mortality, the program initiated in 1990 will prevent 400 to 450 hepatitis B-related deaths in future years.

Mr. NIELSON. You indicated areas and populations for hepatitis B is highly endemic. What consideration has CDC given to those areas?

Mr. HINMAN. We believe that it is appropriate that in such areas, which include, for example, Alaska and some of the Pacific Basin territories or commonwealths, that universal immunization of infants is appropriate.

Mr. NIELSON. If you adopted universal immunization of infants by CDC, what would be the impact on disease prevention, in your estimation, by 2000 or 2015?

Mr. HINMAN. I will have to provide you that number, sir. I don't have it in my head.

[The following response was received:]

If universal routine infant hepatitis B immunization was implemented in 1991, it is estimated that 22,830 infections and 5,070 hepatitis B virus (HBV) carrier infections would be prevented annually by the year 2000. By the year 2015, it is estimated that 103,980 infections and 12,290 HBV carrier infections would be prevented annually.

Mr. NIELSON. How many States require an administration fee for the vaccines that you provide?

Mr. HINMAN. We will have to provide that number, sir.

I have to say that it is not uniform within a State. It may vary from county to county. But we will provide that for you.

Mr. NIELSON. Give us the breakdown. I assume some States provide it free and others charge and there are different charges within States.

Mr. HINMAN. That is correct.

[The following response was received:]

The following summarizes the responses of 52 immunization projects within the United States regarding administration fees for immunization and their impact on immunization levels.

A total of 36 (69 percent) of the responding projects indicate that at least one or more of their county health departments (CHD) and/or local public health agencies (LPHA) request a fee for administering project-supplied vaccine. Eighteen projects indicate that more than 75 percent of their CHD and/or LPHA request an administrative fee while nine projects report that less than 25 percent request an administrative fee. The remaining nine projects report that between 25 and 75 percent of their clinics request an administrative fee.

Twenty-four projects request less than $5 per visit, while 10 projects request between $5 and $10 per visit. The remaining 2 projects request between $15 and $20 per visit. In one of these projects, less than 25 percent of the clinics request a fee, while more than 75 percent of the clinics in the other project request a fee. In these projects where public clinics are not available, these higher fees are requested of public sector patients who are furnished immunization services by a private physician who receives free vaccine from the State. No charge is requested for the vaccine.

None of the 36 projects indicated that immunization services would be denied if the patient did not pay.

When asked if immunization fees contribute to lower immunization levels in the project, nine, or 17 percent of the projects responded in the affirmative.

Mr. NIELSON. I have other questions but I believe I had more than my share of time, so I will submit the rest in writing.

Mr. WAXMAN. Thank you, Mr. Nielson.

Dr. Rowland.

Mr. ROWLAND. Thank you, Mr. Chairman.

I understand that as of yesterday my own State of Georgia is going to require vaccination for H. influenza, which is the most common cause of meningitis in 6 to 18 months of age. Is the money available to pay for this vaccine or do we have a stockpile of vaccine in the State of Georgia to deal with this now? And how many other States are requiring H. influenza vaccination?

Mr. HINMAN. I can answer portions of the question and I will ask Dr. Orenstein to answer the rest.

There is support in the budget to purchase the needed number of doses of *Haemophilus B* conjugated vaccine.

Mr. ROWLAND. The State budget?

Mr. HINMAN. No, sir. In the President's budget there is support for purchase of essentially the standard fraction of *Haemophilus* conjugated vaccine.

Haemophilus vaccine is not presently in the stockpile. The stockpile is a national stockpile; it is not a State stockpile. We do not currently have any *Haemophilus* conjugated vaccine in the stockpile.

As far as the number of States requiring *Haemophilus* as a condition of entry to day care centers or preschool, Dr. Orenstein can respond to that.

Mr. ORENSTEIN. First of all, I think it is important to point out that *Haemophilus* is a disease that strikes before school entry. So school entry laws would not be appropriate.

There are 10 States that have day care regulations requiring *Haemophilus influenza B.*

Mr. ROWLAND. By the time you get to be 6 years old you have passed the danger period.

Mr. ORENSTEIN. Exactly. So our major focus is on day care. Ten of the 51 jurisdictions, the 50 States and the District of Columbia, have regulations for *Haemophilus influenza B.*

Mr. ROWLAND. If it is not stockpiled, how will the requirements of these States that now have this in place be met?

Mr. HINMAN. It would depend on continuing manufacture.

Mr. ROWLAND. You mentioned a few moments ago that a couple of companies have come together now to manufacture vaccine. You were not sure what the liability problem has to do with the decrease in the number of companies that manufacture vaccines. That was a significant problem, as I understand it, at one time.

Mr. HINMAN. It certainly was mentioned by companies as a major reason for the increase in vaccine prices, which really skyrocketed during the 1980's. Whether this really was a major factor in the number of companies active in the marketplace is difficult to know. One manufacturer who discontinued the manufacture of DTP vaccine mentioned liability as one of the reasons but not the reason.

Mr. ROWLAND. Do you think the vaccine compensation legislation that was put in place has been helpful?

Mr. HINMAN. I think it is a little early to make final judgments. There were a lot of problems in the initial implementation of the program. Some technical amendments that were enacted at the end of the last session have helped considerably. Certainly the impression of the people in the program is that it is functioning more smoothly now.

Most of the experience to date has been with claims for injuries occurring before the program became effective and there are some differences in how those can be handled compared to those that occurred after the program became effective.

The short answer is, I think, there is optimism but it is too early to really make a conclusive statement as to whether it has been helpful. There certainly has been a stabilization in price of vaccines.

Mr. ORENSTEIN. There has been a decrease, at least through 1988, in the number of lawsuits filed against DTP vaccine manufacturers and a graph of that is in the testimony that was submitted.

Mr. ROWLAND. Has there not been a huge increase in prices recently?

Mr. HINMAN. We can provide data on the prices of vaccines. In fact, we have had a stabilization. DTP has declined slightly. Measles, mumps, rubella vaccine declined slightly from last year's contract to this.

Table 5 in the testimony shows how the price of these vaccines has varied since 1980 to the present time.

DTP vaccine skyrocketed during the 1980's from 15 cents a dose in 1980 to our current price of $7.96, but during the last 3 years the price has been relatively stable and actually our current price is lower than the price in 1988. We were paying $8.45 a dose at that time. We are now paying $7.96.

Oral polio vaccine has gone up, in 1988 to 1989, from $1.36 to $1.92 a dose. In the current year our price is the same.

MMR vaccine increased during the decade of the 1980's from $2.71 a dose in 1980 to a peak of $16.18 a dose in 1988 and 1989, but in our current contract, it has reduced slightly to $14.71.

Mr. ROWLAND. Let me ask you something about pertussis. You mentioned that earlier. As I recall, pertussis vaccine is one that has the most serious side effects. Were you saying something earlier to the effect that that vaccine may now or in the near future be safer than it has been?

Mr. HINMAN. Our highest priority in vaccine development is the development of improved pertussis vaccine. We have sponsored field trials in Sweden. The Public Health Service, the National Vaccine Program, are currently sponsoring evaluations of some nine candidate pertussis vaccines. It is our hope that one or more

of these may prove to be comparably effective to our current vaccine and less associated with adverse events.

Mr. ROWLAND. I am pleased to hear that, because I have known of some instances where there was some brain damage attributed to the pertussis vaccine.

Mr. HINMAN. It has been very difficult to try to sort out whether the brain damage that has been attributed to pertussis vaccine was actually caused by pertussis vaccine. There remains substantial debate about that.

Mr. ROWLAND. I have one additional question about the measles vaccine and the fact that protection decreases with increasing age and college-aged students now are susceptible to measles. Is there some variation in individuals? Is it relative to the vaccine itself or to the individuals? Why does this come about?

Mr. HINMAN. The primary problem does not appear to be loss of immunity in persons who were once protected and then lose protection. If that occurs, it seems to be a minor part of the problem that we see of vaccine failure. The primary problem seems to be that these children were not protected with the first dose for reasons that we can't totally explain. Some of them may have had continued circulation of maternally derived antibody. We just don't know. But overall, somewhere between 2 and 5 percent of children who receive measles vaccine will not be protected. It is our best estimate that about 95 percent of those children will be protected by the second dose.

Mr. ROWLAND. Would you make some comment about the immunization with the measles vaccine and women of childbearing age, which college students would be?

Mr. HINMAN. We have no information to suggest that there is any risk from measles vaccine administered in a pregnant woman. Nonetheless, we recommend that women who are pregnant not receive live-virus vaccines, generally. However, we have no evidence that there is a hazard if they are vaccinated when they don't know that they are pregnant.

Mr. ROWLAND. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Dr. Rowland.

Under the Vaccine Compensation Program, HHS is required to provide information to the public about the availability of the program. I understand this information campaign has not gone out. I would like to know why not? When can we expect the campaign to begin?

Mr. HINMAN. I will be pleased to provide that information for you. I don't have an immediate answer.

Mr. WAXMAN. We would like to have that.

[The following response was received:]

As required by the Notice of Proposed Rulemaking (NPRM) process, a period for comment and a public hearing were held to consider drafts of the Vaccine Information Materials which appeared in the March 9, 1989, "Federal Register." Initial response to the draft materials clearly indicated a need to revise the materials to make them both shorter and easier to read and understand. On August 28-30, 1989, a working group of experts representing parent organizations and National and State health organizations and agencies was convened at the Centers for Disease Control to review the public comments and to recommend necessary revisions of the materials. Revisions of the vaccine materials developed at this workshop have been reviewed and further revised. The latest drafts were forwarded to the Advisory

Commission on Childhood Vaccines (ACCV) on October 26 (DTP) and December 20 (MMR and Polio); comments are expected in April. A final draft of the materials will be submitted for publication as a "Final Rule" which will be published in the "Federal Register." From that publishing date, 6 months will be allowed until the Vaccine Information Materials must be in use in both the private and public sectors. It is expected that the materials will be in use by the end of 1990.

Mr. WAXMAN. Mr. Sikorski, do you have any questions?

Mr. SIKORSKI. I have no questions, Mr. Chairman.

Mr. WAXMAN. Dr. Hinman, let me suggest that the diplomatic way in which you answered some of these questions, telling us what the needs were and still staying consistent with representing the administration's request for even less money is a sign to me that for your next career you might consider the State Department.

You have been very diplomatic.

Mr. HINMAN. Thank you, sir.

Mr. WAXMAN. We appreciate your testimony.

Thank you, Dr. Orenstein.

Our second witness is Ms. Kay Johnson, director of the health division of the Children's Defense Fund, a research and advocacy group concerned with issues confronting America's children. Among these is the problem of access to primary and preventive health services, including childhood immunizations.

The availability of and access to vaccine shots for infants and children has been a top priority for Children's Defense Fund over the last several years. It has issued a number of reports which indicate that for some populations childhood vaccinations are not routine. These reports show, too, that our progress in meeting the national goal of immunizing all children against preventable diseases has slowed. Ms. Johnson has done much of this work for the Children's Defense Fund. We are pleased to have you with us today.

Your prepared statement will be in the record in its entirety. We would like to ask you to limit your oral presentation to no more than 5 minutes.

STATEMENT OF KAY JOHNSON, DIRECTOR, HEALTH DIVISION, CHILDREN'S DEFENSE FUND

Ms. JOHNSON. Mr. Chairman, thank you for that kind introduction. I am very pleased to have this opportunity to appear before you and the members of the committee on behalf of the Children's Defense Fund. CDF is a national private charity that provides long range and systematic advocacy on behalf of children.

In the context of our overall concern for health access, we are particularly concerned about low income children. We have been monitoring and studying the immunization status of American children, and in recent years our concern has grown as the immunization rates of American children have stagnated or even declined for some crucial age groups. The goal of our immunization work is to ensure that all children have access to appropriate immunizations.

As you know, the use of vaccines to prevent disease has been one of the major success stories in public health and modern medicine. Among the greatest success stories was the eradication of smallpox

and the dramatic reduction in the incidence of polio in the United States.

However, in order to move toward global eradication of diseases such as polio and measles, the United States must take an aggressive lead in immunizing children against preventable diseases. At a time when UNICEF and third world nations are conducting a worldwide campaign to immunize children against preventable diseases, our leadership must not fail our children.

We view this hearing and all of your attendance here today as an indication of your concern and a very important step toward reversing some of the recent trends.

The recent statistics from the Centers for Disease Control indicate that there are cracks in our childhood immunization system. My testimony reviews our failure to meet the Surgeon General's objectives and some of the other problems with the Immunization Program.

Since 1979, we have had a set of national health objectives and they have been set by Surgeons General and reaffirmed by several administrations and by the Public Health Service. In relation to the immunization status of our youngest children, the following goal was set: That by 1990, 90 percent of all children would have completed the basic series of immunization.

Evidence indicates that the Nation will not meet that objective. In fact, many children do not receive vaccine according to schedule and generally only between 70 and 80 percent of children have received the basic series by age 2. In poor innercity areas, less than 50 percent of 2-year-olds are appropriately immunized.

We have a grave concern about the experience of those children. We think this is a reflection of their overall lack of access to health care and that of their families. Many of these children are in the same families where women did not receive adequate prenatal care. We know they are not well linked to the system.

If we use the case of measles as an example, I think that we can see how some of the failures have occurred and what they mean for families and communities.

Before the measles vaccine became available, there were more than 400,000 cases of measles each year. Between 1977 and 1979, we had two dramatic reductions in the numbers of cases of measles. We had dropped from 400,000 cases on average to about 1,400 cases on average.

Those declines occurred primarily as a result of a Measles Elimination Program that was introduced by Federal officials in 1978. The goal of that program was to eradicate measles in the United States by 1982.

I had the pleasure of hearing Dr. Orenstein present testimony yesterday to the National Healthy Mothers-Healthy Babies Committee and say that our goal was still to have measles eradicated by 1982. Somehow we have missed that goal. We haven't even made it by 1990.

As you mentioned, we had an alltime low for measles of about 1,500 cases in 1983 and by last year that had increased tenfold, up to more than 15,000 cases. One-third of those cases were among preschool age children. Many of the outbreaks began with preschool age children living in poor urban neighborhoods. The CDC

has estimated that 80 percent of those reported measles cases among the children 16 months to 4 years could have been prevented if they had been immunized on time.

So this is really a failure of our system to do what we know how to do well already. This isn't one of those intractable problems that we don't necessarily know how to solve.

The outbreaks have human and fiscal consequences. As was mentioned, more than 40 children died last year as a result of measles. This is the greatest number of measles-related deaths since 1971. While we don't have a final cost for these outbreaks, we know that about 10 percent of those children were hospitalized; many of the others had encephalitis and other severe complications that obviously had enormous costs that we will ultimately calculate, I hope. We know that every dollar that we spend on preventable measles or other preventable disease is unnecessarily lost.

We have also had increases in pertussis and mumps, and those are other areas of concern.

As has been mentioned, generally about half of all childhood vaccines are financed through the public sector. We use a combination of public programs to achieve that. The public programs include the Federal Immunization Grants Program that we are talking about today. Also the Medicaid Program, the Maternal and Child Health Block Grant and Community Migrant Health Centers are an important part of the service delivery system for these vaccines.

But the key to the entire system is the Vaccine Administration Program. We have a number of problems that really indicate the depth of our failure and the reasons that the dollars are insufficient currently.

We know that health officials in many cases have reported dramatic increases in demand. Mississippi State health officials report 80 percent of children get their services through local health department clinics. We know that in cities like Los Angeles, Houston and Miami, measles outbreaks have created a public health emergency. And while officials are dealing with that problem, they are not able to go back and improve those low immunization levels that initially led to the outbreaks. Furthermore, we know that in medically underserved areas across the country, Community Health Centers have reported difficulties in securing vaccines.

We believe that Congress and the U.S. Department of Health and Human Services should begin now to adopt policies which can assure an adequate system for childhood immunizations by 1992. Even if we fail to meet our 1990 objectives, let us not wait until the year 2000 to try to achieve them.

We recommend reauthorization of the Childhood Vaccine Program at a level of $230 million. The figures are broken out in my testimony. We will also be supporting full appropriation for this program, enactment of Medicaid expansions, support for the Community and Migrant Health Centers so there is someone to administer these vaccines in underserved communities, and the restoration of a national surveillance system so we can track our progress.

In conclusion, I would like to say that while 95 percent of U.S. 1-year-olds had some dose of polio at last count, 14 nations had better progress on polio than the United States in 1988. Moreover, if you look at only our nonwhite population where 82 percent of 1-year-

olds were appropriately immunized, when we compare this, we lag behind nations such as Albania, Tunisia. And in China, 99 percent of all infants have been adequately immunized against polio. We can't even come close to that measure.

We can't afford preventable illness and disability and death among our children. We really need to act now to ensure that all children have access to affordable, safe vaccines and recommit ourselves to the goal of disease eradication whenever possible.

[Testimony resumes on p. 100.]

[The prepared statement of Ms. Johnson follows:]

STATEMENT OF CHILDREN'S DEFENSE FUND

Mr. Chairman and members of the Subcommittee, I am pleased to have this opportunity to appear before you today on behalf of the Children's Defense Fund (CDF). CDF is a national public charity that provides long range and systematic advocacy on behalf of children. We pay particular attention to the needs of low income and minority children. For more than 15 years we have worked to improve the health of poor children by ensuring that they and their families have access to the basics that any child needs to be born healthy, thrive, and grow into productive adulthood: adequate family income, a safe place to live, good schools, a caring and nurturing family, and access to decent health care.

In the context of our overall concern for access to health care, particularly among low-income children, we monitor and study the immunization status of American children. In recent years, our concern has grown as the immunization rates of American children stagnated or even declined for some crucial age groups. The goal of CDF's childhood immunization work is to ensure that all children have access to appropriate immunizations.

The use of vaccines to prevent disease has been one of the major success stories in public health and modern medicine. Among the greatest successes are the eradication of smallpox worldwide and the dramatic reduction in the incidence of polio in

the United States. However, in order to move toward global eradication of diseases such as polio and measles, the United States must take an aggressive lead in immunizing children against preventable disease. At a time when UNICEF and third world nations are conducting a world-wide campaign to immunize children against preventable diseases, U.S. leadership must not fail our children. We view this hearing as an indication of your concern and a positive step toward reversing recent trends.

To protect public health, a high level of immunization throughout the population must be achieved and maintained to prevent outbreaks of vaccine-preventable disease. High immunization rates play two important roles. First, they are crucial for protecting persons (particularly infants) not fully immunized. Second, only a consistently high rate of immunization ultimately can lead to the complete eradication of a disease. Thus the system for childhood immunization is crucial for the prevention of infectious disease both on an individual and nationwide basis. The failure of this system leads to preventable disease outbreaks.

Recent statistics from the Centers for Disease Control (CDC) indicate that cracks have developed in our childhood immunization system. My testimony reviews our failure to meet the Surgeon General's immunization objectives for 1990 and statistics on the increasing incidence of preventable childhood disease. It also examines the adequacy of public immunization program funding levels. To close, I will discuss the steps essential to protect all children with immunizations.

I. The Nation Will Fail To Meet Many of the Surgeon General's 1990 Objectives of Immunization.

The U.S. Surgeons General and the Public Health Service have established national health objectives. In relation to the immunization status of our youngest children the following goal has been set:

- By 1990, 90 percent of all children should have completed the basic immunization series by age two (measles, mumps, rubella, polio, diphtheria, tetanus, and pertussis) (See Table 1 for basic series).

All available evidence indicates that the nation will not reach this objective (Table 2).

Statistics indicate that in 1985 a smaller percentage of children age two and younger were fully immunized against polio, measles, rubella, mumps, and diphtheria-tetanus-pertussis (DTP) than in 1980 (Table 3). No state or city statistics suggest that this trend has been reversed.

TABLE 1. Recommended Immunization Schedule for Infants and Children*

Recommended Age**	Vaccines
2 months	Diphtheria, Tetanus, and Pertussis (DTP)-1 Oral Polio Vaccine (OPV)-1
4 months	DTP-2, OPV-2
6 months	DTP-3
15 months	Measles, Mumps, and Rubella (MMR)-1 DTP-4, OPV-3
18 months	Hib Conjugate Vaccine (Hib C-V
4-6 years	DTP-5, OPV-4, MMR-2
14-16 years	Adult Tetanus and Diphtheria (Td)

*Alternative schedules are recommended for children delayed in beginning immunizations and for certain chronically ill children.

**These recommended ages are not absolute. For example, 2 months may be 6-10 weeks of age.

Source: Recommendation of the Immunization Practices Advisory Committee. Morbidity and Mortality Weekly Report, January 14, 1983. Revised September 19, 1986, April 7, 1989 and January XX, 1990.

- **Many children do not receive vaccine according to schedule. Generally, only 70 to 80 percent of children have received the basic series by age two. In poor, inner-city neighborhoods, less than 50 percent of two-year-olds are appropriately immunized.**

TABLE 2. Progress Toward the Surgeon General's Objective for Full Immunization for Children Age Two

Year	POLIO*	MEASLES	RUBELLA	MUMPS	DTP*
1980	80.7	83.0	83.2	80.2	87.0
1981	80.9	81.5	83.9	79.1	87.6
1982	78.6	84.3	81.1	79.0	88.4
1983	78.6	83.9	81.9	78.1	88.4
1984	74.2	81.7	76.7	78.4	85.8
1985	76.7	81.7	77.3	78.9	85.8
1990 Objective	90.0	90.0	90.0	90.0	90.0

*Full immunization at this age is defined as three or more vaccinations.
Source: Centers for Disease Control, U.S. Immunization Survey.

TABLE 3. Percent of Children Age Two Fully Immunized, By Race, U.S., 1980 and 1985

	Polio*	Measles	Rubella	Mumps	DTP*
ALL RACES					
1980	80.7	83.0	83.2	80.2	87.0
1985	76.7	81.7	77.3	78.9	85.8
CHANGE**	-4.0	-1.3	-5.9	-1.3	-1.2
WHITES					
1980	83.0	84.8	84.4	81.5	89.4
1985	79.5	82.7	78.6	80.8	88.0
CHANGE	-3.5	-2.1	-5.8	-0.7	-1.4
NONWHITES					
1980	62.8	69.0	73.4	70.7	68.0
1985	56.5	74.7	66.9	64.2	69.1
CHANGE	-6.3	+5.7	-6.5	-6.5	+1.1

*Full immunization at this age is defined as three or more vaccinations.

**Change in percentage points.

Source: Data from Centers for Disease Control, U.S. Immunization Survey. Based on sample confirmed by records.

- **In addition to a statistically significant drop in the immunization status of two-year-old children between 1980 and 1985, these statistics show a distressingly high proportion of our youngest children (particularly nonwhite children) are not fully immunized against preventable diseases, for example measles.**

II. Recent trends in cases of targeted childhood diseases are troubling.

Measles: Measles, also called rubeola, is a highly contagious viral disease. For most people, measles begins like a cold, with a rash appearing a few days later and lasting one to two weeks. Measles can cause very serious illness. It can lead to middle ear infections, pneumonia (especially in infants), an inflammation of the brain (encephalitis) leading to convulsions, permanent brain damage, or death. Death occurs in one of every 3,000 reported measles cases.

Before the vaccine became available, more than 400,000 measles cases were reported each year. From 1977 to 1978 and again from 1978 to 1979, the number of reported measles cases dropped by half (from approximately 57,000 to 27,000 and from 27,000 to 13,500, respectively). These declines occurred primarily as a result of a Measles Elimination Program introduced by federal officials in 1978 that sought to eradicate measles in the United States by 1982. But after dropping to a low point of about 1,500 cases in 1983, more than 15,000 measles cases were reported in 1989 -- a ten-fold increase.

The recent increases in reported measles cases occurred in all age groups, but nearly one-third of reported cases occurred among preschool-age children. Many outbreaks began among preschool-age children living in poor, urban areas. The CDC has found that more than 80 percent of reported measles cases among children 16 months to four years were preventable through timely immunization.

These outbreaks have human and fiscal consequences. Last

year more than 40 children died as a result of measles -- this is the greatest number of measles related deaths since 1971. Moreover, during the first first few weeks of this year, measles outbreaks seem to have further accelerated. The fiscal cost of these outbreaks has not yet been calculated. However, every dollar spent on preventable measles is unnecessarily lost. Generally, we can save $10 for every $1 we spend on immunizations by averting disease.

Polio: The polio epidemics of the first half of this century resulted in disability for tens of thousands of Americans and deaths for thousands more. Widespread use of the Salk vaccine beginning in the mid-1950s brought about the most visible immunization success story of our time. During the 1980s there was an average of only 10 cases of polio reported each year.

Yet because many cases of polio occur around the world each year and polio is extremely contagious, the need for high rates of vaccination among American children against polio remains critical. Experts warn that, because of the highly contagious nature of polio, the pattern of measles outbreaks among preschool age children could be repeated in the case of polio.

Mumps: Mumps is a communicable disease that, in younger children, usually causes mild symptoms, including fever and and inflammation of the neck and face. Sometimes it has more serious complications, and mumps can be a serious disease among adults.

In 1986, after 15 years of almost continuous decline in the reported incidence of mumps, the number has begun to climb again since the mid-1980s. The number of cases of mumps doubled between 1985 and 1986 (from 2,982 to 7,790 cases, respectively).

Furthermore, by 1989 the number of reported cases of mumps remained over 5,000. The CDC statistics suggest that recent increases largely have been a result of illness among unvaccinated teens, however preschool age children also are affected.

TABLE 4. Trends in Reported Cases of Selected Diseases, U.S., Selected Years 1960-1988

Year	POLIO	MEASLES	RUBELLA	MUMPS	DIPHTHERIA	TETANUS	PERTUSSIS
1960	3,190	441,703	---	---	918	368	14,809
1965	72	261,904	46,975*	152,209**	164	300	6,799
1970	33	47,351	56,552	104,953	435	148	4,249
1975	8	24,374	16,652	59,647	307	102	1,738
1980	9	13,506	3,904	8,576	3	95	1,730
1981	6	3,124	2,077	4,941	5	72	1,248
1982	8	1,714	2,325	5,270	2	88	1,895
1983	15	1,497	970	3,355	5	91	2,463
1984	8	2,587	752	3,021	1	74	2,276
1985	7	2,822	630	2,982	3	83	3,589
1986	10	6,282	551	7,790	0	64	4,195
1987	6	3,655	306	12,848	3	48	2,823
1988	9	3,396	225	4,866	2	53	3,450
1989	na	16,236	na	5,611	na	na	3,745
1990 Objective	10	500	1,000	1,000	50	50	1,000

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* Number is for 1966, the first year that rubella cases were routinely reported.
**Number is for 1968, the first year that mumps cases were routinely reported.

Source: Data from Centers for Disease Control. Summary of Notifiable Diseases, United States, 1988, October 6, 1989.

- **Certain disease rates are increasing and at current rates of progress, the United States will not meet the Surgeon General's Objectives for reduction of disease rates for measles, mumps, and pertussis.**

Rubella: Rubella, also called German or three-day measles, is generally a mild but highly contagious viral illness for children. However, where rubella spreads to teenagers and young adults, it can infect pregnant women and cause miscarriage, stillbirth, or multiple serious birth defects.

The last big epidemic of rubella was in 1964-1965, when an estimated 12.5 million cases, more than 11,000 fetal deaths, and 20,000 instances of birth defects from congenital rubella occurred. By 1988, there were only 225 cases of rubella. In that year, there were 6 cases of congenital rubella syndrome reported (this number has shown wide fluctuation in recent years).

Diphtheria: Diphtheria is an infectious disease caused by a bacterium found in the mouth, nose, and throat of infected persons. In some cases, especially when untreated, diphtheria can produce a toxin that may spread throughout the body and cause serious complications.

Widespread immunization against diphtheria has greatly reduced the number of reported cases. In the 1920s, approximately 150,000 to 200,000 cases of diphtheria and 15,000 to 20,000 related deaths occurred annually. No more than five cases were reported in any year between 1980 and 1988. However, the fact that diphtheria resulted in the death of one child in Florida early this year is evidence of the need for constant vigilence in protecting children against this disease.

Tetanus: Tetanus, also known as lockjaw, is caused by a bacterium that exists in virtually every part of the environment.

In the 1940s more than 600 cases of tetanus often were

reported in a year. In the past decade, the incidence of pertussis has averaged about 70 per year. Currently, most cases (95 percent) occur among adults.

Pertussis: Pertussis, commonly known as whooping cough, is a highly contagious disease caused by a bacterium found in the mouths, noses, and throats of infected persons. For children younger than two, pertussis can be quite serious. It is fatal for 1 to 2 percent of infected infants, but even children who survive may be left paralyzed, mentally retarded, or otherwise impaired.

The pertussis vaccine used today is made of whole, killed bacteria and contains agents that may cause adverse reactions for some individuals. Furthermore, the currently used pertussis vaccine does not provide complete immunity. Research is currently under way to improve the pertussis vaccine.

The incidence of pertussis dropped from a reported high of more than 250,000 in 1934 to a low of 1,248 cases in 1981. It is of great concern, however, that the number of reported cases more than tripled between 1981 and 1986, reaching 4,195 -- the highest reported number since 1970. Since 1986, numbers of cases have remained far above the 1981 all-time low. Rates of pertussis were especially high among infants.

III. **Funding for immunization efforts has failed to keep pace with vaccine price inflation.**

Generally, about one-half of all childhood vaccines are financed through the private sector -- either out-of-pocket or through private third-party (insurance) payments. The remaining half is financed publicly through a combination of federal and

state programs. These public programs include the federal immunization states grants program (Section 317 of the Public Health Service Act), Medicaid (immunizations are a required service for all Medicaid-enrolled children), the Title V Maternal and Child Health Block Grant program, and the Community and Migrant Health Centers programs.

The Division of Immunization of the CDC serves as the federal agency most directly involved in the prevention and control of preventable childhood diseases. The CDC efforts are carried out through: 1) the program of project grants, and 2) direct program operations. The grant activities are structured under Section 317 of the Public Health Service (PHS) Act and provide for grants to state and local health agencies to allow them to plan, develop, and implement immunization programs.

The key to the entire system of vaccine purchase and administration is the Section 317 federal grant program to the states. But throughout the 1980s these grants have not been adequate to meet the need (Table 5). Despite skyrocketing vaccine costs, neither the Reagan Administration nor Congress moved to expand funding levels significantly until FY 1985. Indeed, for FY 1982 the Administration proposed completely eliminating the program (by replacing it with a multipurpose block grant) and then cutting overall funding by 25 percent. Moreover, Congress did not exempt immunizations from the Gramm-Rudman-Hollings automatic spending reduction requirements, and as a result the program suffered across-the-board cuts in funding for FY 1986 and FY 1990.

Table 5 Immunization: Funding and Budget Requests, FY 1981-1991
(in millions of dollars)

	Immunization [1]
FY 1981 actual	$31.0
FY 1982 proposed	--[2]
FY 1982 actual	34.6
FY 1983 proposed	28.9
FY 1983 actual	39.0
FY 1984 proposed	41.9
FY 1984 actual	41.9
FY 1985 proposed	46.0
FY 1985 actual	54.0
FY 1986 proposed	54.0
FY 1986 actual	57.0
After Gramm-Rudman	56.9
FY 1987 proposed	56.0
FY 1987 actual	87.3
FY 1988 proposed	94.0
FY 1988 actual	98.0
FY 1989 proposed	102.0
FY 1989 actual	142.0
FY 1990 proposed	138.0
FY 1990 actual	156.2
FY 1991 proposed	152.7

[1] Includes not just grants but also surveillance and stockpile funds.

[2] Proposed to repeal, include in block grant; funding would have been cut by 25 percent in FY 1982.

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While Congress has expanded program funding during recent years, these increases have not been adequate even to cover the cost of increases in vaccine price inflation and additional numbers of children seeking services in the public sector. Additional dollars have not come close to being sufficient to fight disease outbreaks, support thorough distribution of new vaccines, or provide for outreach to children in underserved communities. The following examples demonstrate the breadth of unmet need.

- At the beginning of 1990, the cost of a basic series of immunizations in the public sector was approximately $85, compared to a private sector cost of over $150 (Table 6).
- Health officials in many states have reported dramatic increases in demand for the publicly-purchased immunizations in available at free or reduced cost in local health departments. In Mississippi, state health officials report that approximately 80 percent of children receive vaccinations in local health department clinics.
- The new Hib-conjugate vaccine available to protect children against meningitis is recommended for all toddlers in group child care settings. However, due to inadequate funding to implement new requirements, by 1989 only 10 states had moved to mandate Hib immunizations. Moreover, this protection had not been routinely assured even for children in Head Start.
- Among low-income and minority children in our nation's cities, only about one-half recieve the basic package of immunizations by age two leaving them susceptible to preventable disease.
- In cities such as Los Angeles, Chicago, Houston, and Miami measles outbreaks have created a public health emergency. With all available personnel and resources being needed to fight a disease outbreak, public health officials are unable to improve the lwo immunization levels that initially led to the outbreaks.
- Serving medically underserved areas across the nation, federally-funded community health centers report difficulties in securing publicly-funded vaccines. Without the ability to buy vaccines at the lower-cost, bulk rate, centers often are unable to offer immunization services.

IV. Recommendations

There has been a substantial increase in the United States in the rate of measles and a resurgence of cases of mumps and pertussis. Immunization rates for our youngest children have leveled off or declined; and, if recent trends continue, the nation will fail to meet about half of the Surgeon General's 1990 objectives in the area of immunization.

Because childhood immunization must be a national priority if we are to eliminate preventable disease, for children in families with income below the federal poverty, vaccines should be made available at no cost. Moreover, for all other children vaccines should be made available at an affordable cost. Ensuring access to immunization and other preventive child health services

Congress and the U.S. Department of Health and Human Services should begin now to adopt policies which can assure an adequate system for providing childhood immunizations by 1992. Meeting the Surgeon General's Objectives, by even that year, will require a commitment such as was made during the late 1970s, including: continued increases in funding levels for key child health programs to ensure that vaccines are accessible to all children; aggressive efforts to improve and sustain immunization levels; studies of disease outbreaks and their causes; public education campaigns regarding the importance of childhood immunizations; and ongoing surveillance of a detailed nature.

To achieve all of our national immunization goals, CDF recommends the following:

o **Reauthorization of the Childhood Vaccine Program** with the following funding levels:

- $150 million for FY 1991 and such sums as necessary in years thereafter for grants to states for purchase of vaccine (includes $50 million for FY 1991 to purchase the newly recommended second dose of measles);
- $30 million for the Infant Immunization Initiative;
- $15 million for disease outbreak control;
- $10 million for implementation of a Hepatitis B vaccine effort;
- $5 million for parent information materials; and
- $20 million for state operations.

o **Appropriation of sufficient funds in the Immunization Program to enable the CDC to make vaccines available to all children.** Funds appropriated for FY 1989 should allow CDC to continue support for the national immunization system, not just for the purchase of vaccines. Funds to purchase a sufficient number of doses of vaccine are essential, as is having a sufficient number of health care providers available to vaccinate children. However, direct service delivery is only one aspect of our national system. The CDC also has responsibility for program operations including: coordination, surveillance, outbreak control, education and outreach, and other public health supervisory activities. A continued commitment to maintenance of the vaccine stockpile also is essential.

o **Enactment of H.R.931 and H.R. 3932 the Medicaid Infant Mortality and Child Health Amendments of 1988.** These bills would

extend Medicaid coverage to additional infants and children in low income families and thereby ensure the financing of immunizations for tens of thousands of children. The Medicaid expansions, by providing families with a way to pay for services, also may help families continue their relationships with private pediatricians.

o **Community and Migrant Health Centers should be encouraged to participate in bulk, public purchase of vaccines.** Because millions of children recieve primary care services from these comprehensive centers located in rural and urban medically underserved areas, ensuring an adequate supply of vaccines to health centers is a key step toward improving immunizations in such communities.

o **Restoration of the immunization surveillance system or replacement of the prior system with a new annual immunization survey.** Since 1985, the federal government has conducted no national surveys regarding children's immunization status. Given certain adverse trends in immunization status and recent outbreaks of diseases across the nation, abandoning this surveillance is a serious mistake in public health terms. Comprehensive surveillance activities, based on a national survey, should be resumed immediately to chart progress for the next decade.

V. Conclusions

While 95 percent of U.S. one-year-olds were immunized against polio at last count, 14 nations had better rates in 1988. Moreover, when the U.S. nonwhite population's rate (82 percent of one-year-olds appropriately immunized against polio) is compared with other nation's overall rates, the United States lags behin 48 other countries, including Albania, Tunisia, and China.

This nation cannot afford preventable illness, disability, or death among our children. We must act now to ensure that all children have access to affordable, safe vaccines and recommit ourselves to the goal of disease eradication where possible.

REFERENCES

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Johnson K. Who is Watching Our Children's Health? The Immunization Status of American Children. Children's Defense Fund, Washington, DC, December 1987.

The majority of the statistics presented in that report and in this testimony came from the Centers for Disease Control (CDC). All references to immunization status and the U.S. Immunization Survey are from unpublished tables prepared by the Centers for Disease Control. Calculations of the percentage of children immunized by age were done by the CDC, and calculations of the percentage change over time were done by CDF.

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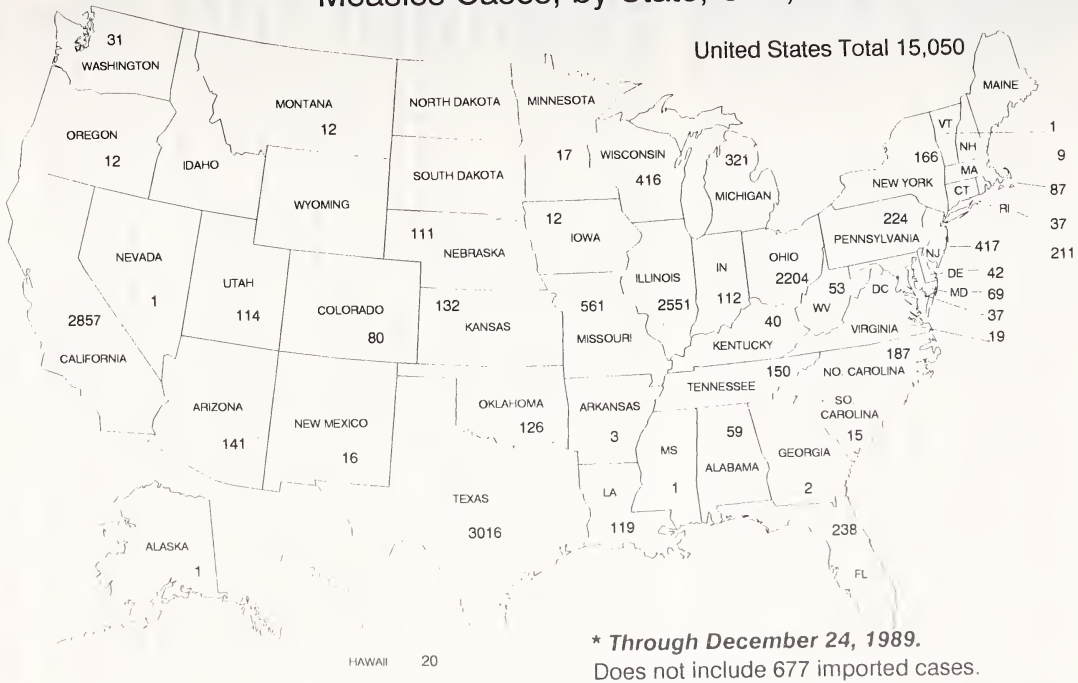
Measles Cases, by State, U.S., 1989 *



**** Through December 24, 1989.***

Does not include 677 imported cases.

State numbers do not include out-of-state cases.

Source: Centers for Disease Control

Mr. WAXMAN. Thank you very much for that excellent statement.

The Children's Defense Fund has done a lot of work in looking at immunization programs and immunization rates throughout the country. It is clear from your work that the message about the importance of immunizations is not getting to all the parents and children it should. Children who should be immunized are going without needed shots.

What is the problem? Who are these children? Why aren't they being immunized? Is it simply a matter of dollars?

Ms. JOHNSON. I think it is not simply a matter of dollars but there are several pieces that fit together. There is an issue around dollars. If all of these children were coming to local health departments to be served and we were addressing this problem in kind of a status quo approach, saying we need the same number of vaccines this year and we have 30 percent of the children who haven't yet come in, we need more money to serve the other 30 percent of the children.

In addition to that, we have a situation where at the local health department level they may not be prepared to serve those children where those children do not have a regular source of care. For a child who regularly sees a pediatrician, it is not the family's problem to remember the immunization; it's the regular provider who remembers that. So linking these children up to a regular source of health care and to the family is very important.

We know these children are more likely to have mothers who didn't receive prenatal care; they are more likely to have low income, low socioeconomic status generally, low parental education. But I don't think we need to depend on educating every family. We need to try to work to link these families up to a regular source of care so that the professionals can take that responsibility.

Mr. WAXMAN. You point out in your written testimony that the Childhood Immunization Program is not exempted from the Gramm-Rudman sequestration requirements. Has this had an effect at the State and local level in disrupting services? Has it meant that some years, even the Congress has not kept up with the inflation costs in vaccine prices?

Ms. JOHNSON. It certainly has meant that we have not kept up with vaccine inflation prices, particularly during the mid-1980's. If we continue to have large sequestration effects in the next few years, we will continue to see a problem in the Immunization Program.

The actual dollars is one problem. Another problem is the effect it has at the community level. Where the local health department suspects that there is going to be a cut coming down the road, they aren't planning for an aggressive outreach program to go out and find those children who are not immunized. They aren't planning for the way that they are going to do outbreak control in Los Angeles or in Chicago, because they are worried that the dollars simply will not be there, and they suspend those activities. So it disrupts the local public health activity, certainly.

Mr. WAXMAN. You mentioned that the Community Health Centers are an important point for providing childhood immunizations.

Is the Federal Government doing what it can to ensure that these programs provide immunizations?

Ms. JOHNSON. No. Unfortunately, because the Community Health Centers are part of a Federal system and operate under Federal grants, they are not linked always to the State health department. That is the routine location for a clinic to seek that linkage to the publicly purchased vaccines. So the dollars go out to the State health department but that Community Health Center is not linked to the local health department.

If there were more collaboration at the Federal level between the Public Health Service and CDC about getting those bulk purchase vaccines directly to these federally funded centers, it would be a much more efficient system.

Mr. WAXMAN. You have noted that the Federal Government has stopped conducting national surveys regarding children's immunization rates. Why is it important that such information be available?

Ms. JOHNSON. My concern grows out of the research that I did based on the statistics from 1980 to 1985. When I looked at what had happened between 1980 and 1985, I found that there was a significant decrease in the proportions of 2-year-olds who had been immunized.

In 1985, the CDC ceased its contract with the Bureau of the Census and is no longer collecting national statistics. We have no idea what has happened to the immunization status of children at those young ages unless they went into a licensed day care center or until they entered school.

It is absolutely imperative that at a time when we have measles, mumps and whooping cough outbreaks that we know what is happening to children's immunization status. We can't possibly fix problems if we can't document what the problem is.

There has been a suggestion that the National Health Interview Survey would be a very important place for questions about immunization to be added. We have waited 5 years. No questions have yet been added. It will be well into the 1990's before we have any. We may go as long as a decade ultimately with no national surveillance on immunization. It is absolutely an important factor.

We have begun in that same time period to do surveillance on the issue of AIDS. It seems to me this is equally as important as our AIDS surveillance and we should be doing both.

Mr. WAXMAN. Thank you very much, Ms. Johnson.

Mr. Nielson.

Mr. NIELSON. I enjoyed your testimony. I have several questions to ask you and I am going to ask some of the same ones to Dr. Peter when he testifies on panel IV.

What is the chief reason parents fail to immunize even when they are available?

Ms. JOHNSON. Again, there are two things that are going on here. One is that there is a very small number of parents who actually are abstaining. But if we look at the statistics, we find that about 95 percent of children get one dose of something but they don't come back in; they don't get followed up; they don't get the whole series. If they don't get the whole series, they are not protected. We may get them one dose of DTP or polio when they are an infant.

Mr. NIELSON. Why do the parents fail to take advantage of it?

Ms. JOHNSON. They may not have a regular source of care and this specific preventive component may not necessarily be obviously important to them. There are also long waits at local health departments. It may take all day for the parent to be there and to bring the child in. There may be no evening hours for a working parent to bring a child in.

Increasingly it has become difficult in some communities to find an outside provider. Where you don't have any private pediatricians or private family practitioners operating in a community, the family can't go outside of that source and seek care.

Mr. NIELSON. Do you think we could do a better job of advertising and making known the services available?

Ms. JOHNSON. I certainly think we could. Congressman, I have something I would be happy to share with you at the end of this session. We think this is so important that we at the Children's Defense Fund have launched a media campaign.

Mr. NIELSON. That was my next question. What is your organization doing to promote this?

Ms. JOHNSON. We have launched a media campaign. It has been running in six cities. It has been running in Los Angeles, in Houston, in Miami, in northern New Jersey, in the Newark area, as well as in Cleveland and Minneapolis. We have paid for the development of the materials and sending them out all over to these communities.

We also have a set of radio public service announcements that we have just distributed to over 250 radio stations across the country, and we will be distributing them, hopefully, to about 1,000 more and maybe a dozen more communities with posters.

We think it is very important, particularly in cities where families may need a little extra urging, that we have this kind of campaign going on.

Mr. NIELSON. I find it surprising that 3 years after my grandson got this problem with meningitis that young mothers of children that same age were not even aware of the possibility of immunization. Even today, 3 years later, most of the mothers with children in the ages 1 to 3 are not aware that they need to have that done.

What can we do to get the *Haemophilus* vaccine mentioned so they know that it is available?

Ms. JOHNSON. I think there are two problems with *Haemophilus*. I think one is the name. We have started to call it the meningitis vaccine. I think that helps a little bit.

Mr. NIELSON. That is better.

Ms. JOHNSON. When we call it something that people can understand I think that helps promote it.

We also know that in the case of other vaccines where we have had the State take action and make a requirement and reinforce the recommendation, we have had a lot more success. So if more than 10 States were setting this forth as a priority, we would have success.

I have to say, however, in defense of the States, I think their concern over their ability to supply the vaccine has kept them from moving forward.

Mr. NIELSON. Do the States have any programs other than the CDC program? Do they initiate some programs in addition to that?

Ms. JOHNSON. Yes. Actually, there are considerable State dollars that flow into this program. I am sure our Florida State health officer will be happy to describe that to you.

Mr. NIELSON. Would you supply for the record which States are doing it and which are not?

Ms. JOHNSON. I would be happy to.

Mr. NIELSON. You mentioned that they should have vaccination or immunization records when they go to day care or preschool. How would you propose we implement that?

Ms. JOHNSON. I worked in child care programs for about 10 years and that is one of the reasons I understand that part of the system well. Where we have good State standards that support the full documentation of immunization before a child enters a group child care program or group preschool or whatever, we have very good compliance. It looks just like the school numbers. We get 95 to 99 percent of children immunized.

Mr. NIELSON. What about the children that don't go to day care or preschool?

Ms. JOHNSON. For the children who do not, I think that this Infant Immunization Initiative that has been put together by the Centers for Disease Control is extremely important. They will be educating communities, educating providers, trying to put together a national coalition of organizations who can, through their affiliates, try to promote immunization. They are also spending money on research to figure out what does work in terms of reaching hard-to-reach families.

Mr. NIELSON. I notice your request is about $35 million more than the chairman was going to put in his bill. Would you like to submit details on how you come up with the number $250 million?

Ms. JOHNSON. I would be happy to.

Mr. NIELSON. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Nielson.

Dr. Rowland.

Mr. ROWLAND. You made a statement a little bit ago that was surprising to me. Let me be sure I heard it correctly. You said that in China 99 percent of infants have been immunized against polio.

Ms. JOHNSON. Yes. That is a UNICEF number. The basis of that is independent research conducted on behalf of UNICEF in China.

Mr. ROWLAND. Is that the People's Republic of China?

Ms. JOHNSON. Yes.

That number was given to me by Dr. Foege at the Carter Center and then it was published in the UNICEF document "The State of the World's Children." They have achieved very high immunization rates among infants.

There are a number of other countries, Dr. Rowland, where that is the case, where they are up above 95 percent. It is absolutely startling the degree to which developing countries have been able to make this a priority and move ahead. I very much want the United States to be competitive in this arena.

Mr. ROWLAND. I do too. It was just curious to me how you get that kind of information out of the PRC.

Maybe Mr. Nielson has already asked this question, but do you know how many States have health departments that operate immunization programs?

Ms. JOHNSON. Every State health department has an Immunization Program. In a number of them, they have quite a few staff slots that are funded by the State dollar itself; others have technical support that comes from the Centers for Disease Control through the State operations funding. But in every State, there is such an office and they are very essential to our linkage, particularly in terms of outbreak control.

Mr. ROWLAND. Do you know if there are instances where immunizations are desired for children and are not available to them for whatever reason?

Ms. JOHNSON. On a long term basis, no. On a short term basis, there certainly are communities around the country where there are considerable waits for appointments to get into an immunization clinic. The clinic may only be 1 day a month or only 1 day a week and the numbers exceed the ability of the clinic on a short term basis to provide that service. A family may be told don't come this Thursday, come a month from today. That is obviously a problem with a family making arrangements.

I think in addition to that we do have a serious problem in terms of identifying families who are culturally and geographically isolated, families who are in the most rural areas and families who are culturally isolated.

In Los Angeles County, I have knowledge of a situation where there are many families who are undocumented, who are isolated from the system, who would not take their children for immunization for fear that there would be a problem because the children were not documented residents. There are those kinds of cultural barriers as well as language barriers for families.

Congressman Waxman asked a question about the parent information materials required under the Vaccine Compensation Program. We have a grave concern that the parent information materials may never be translated into languages that parents in many communities can understand and therefore we will not effectively inform them. In our media campaign at the moment, we have the campaign in both Spanish and English and hopefully we will be able to do more. For example, we want to reach out to the Haitian population in Miami.

Mr. ROWLAND. It seems odd that in a country like China that they could achieve such a high degree of immunization and yet in this country we are not able to do that. I would say that we are much more developed throughout our country than the PRC is.

Ms. JOHNSON. It is absolutely true. I believe that the emphasis that we place on public health has something to do with the situation that we face.

We also have not dealt with our whole country as a hard-to-reach population whereas in China they view the whole problem and the whole system. Reaching into very underserved communities is not always a priority in our public health funding.

I will give you an example. I wish Dr. Orenstein were here to confirm this account of a story. Dr. Orenstein worked in the Measles Elimination Program in the late 1970's in Chicago. One of the

things he has reported to me that he did as an immunization officer at that time, working for the CDC, was going door to door in housing projects, knocking on the door and immunizing the child on the spot. Through the 1980's we have not seen any such effort similar to that. That is what it takes sometimes to get this job done.

Mr. ROWLAND. You mentioned some cultural differences. Is there some problem with fear of vaccination, to your knowledge?

Ms. JOHNSON. I believe there are problems around fear of vaccination. One of our public service announcements addresses that. But I think the greater problem is actually bringing the family to the services and assuring them that there is a system of followup so even if the health department gives one shot, how are they going to notify the family when the next shot is due? There ought to be simple ways that we could do that. That is one of the things that the CDC has hoped to fund with the Infant Immunization Initiative.

Mr. ROWLAND. Would you say that the problem then is not relative to the lack of vaccine itself but to various other things that you have mentioned, like cultural differences and the education of the people that need vaccination?

Ms. JOHNSON. And access to care. In general that is true. I would not want to leave you, however, with the impression that I was not concerned about the vaccine stockpile and the limited number of manufacturers that exist.

Mr. ROWLAND. Thank you.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Dr. Rowland.

Mr. Sikorski.

Mr. SIKORSKI. I find it frustrating that we are dealing with 1950's problems in the 1990's. It is great that your point of light is doing immunizations but it is shameful that these thousand points of light aren't dealing with new problems.

You have very restricted and hard pressed resources. There are major problems in child care and a host of things that are you dealing with. You have to go back and retrench and get resources to do outreach media campaigns when our own Public Health Service tells us we are back at the peak on measles and yet there is no money in the budget to deal with that public health crisis that should have been addressed 2 decades ago, and really was, and now we are back dealing with it again.

I commend you and your organization for doing such good work. I am saddened by the fact that your resources are used up when they should be used on some of the other problems affecting children.

Ms. JOHNSON. Thank you.

Mr. SIKORSKI. Thank you, Mr. Chairman. And shame on the administration.

Mr. WAXMAN. Thank you, Mr. Sikorski.

Ms. Johnson, thank you very much for your presentation to us. We are looking forward to working with the administration. I don't know that they had the figures before they came out with their budget. So on this rare occasion I will defend them.

Ms. JOHNSON. Thank you.

Mr. WAXMAN. Appearing on our third panel are two hands-on public health officials who administer State and local immunization programs and are responsible for dealing with major disease outbreaks such as the measles epidemic that is now occurring around the country.

Dr. John J. Witte is assistant health officer for disease control and AIDS for the State of Florida. Dr. Witte is appearing today on behalf of the American Public Health Association.

And from the San Antonio Metropolitan Health District, we will be hearing from Dr. Fernando Guerra, who is the district's health director.

I want to thank both of you for being here today. We have your prepared statements and will make them part of the record in full. We would like to ask you to limit your oral presentation to 5 minutes.

Dr. Witte.

STATEMENTS OF JOHN J. WITTE, ASSISTANT HEALTH OFFICER FOR DISEASE CONTROL AND AIDS, STATE OF FLORIDA, ON BEHALF OF THE AMERICAN PUBLIC HEALTH ASSOCIATION AND FLORIDA DEPARTMENT OF HEALTH AND REHABILITATIVE SERVICES; AND FERNANDO A. GUERRA, DIRECTOR OF HEALTH, SAN ANTONIO METROPOLITAN HEALTH DISTRICT

Mr. WITTE. Thank you.

Mr. Chairman and members of the committee, I am Dr. John Witte, assistant State health officer for Florida. I am representing the American Public Health Association and Florida's Department of Health and Rehabilitative Services in support of the reauthorization of the National Immunization Program.

For your information, I spent 10 years in the Division of Immunization at the Centers for Disease Control, including 7 years as the director administering the National Immunization Program.

Control of vaccine-preventable diseases is one of the oldest and most successful programs of our Nation's public health care system. The United States has virtually eliminated polio and dramatically reduced the numbers of cases of other vaccine-preventable diseases. The recent death from diphtheria in an unimmunized baby in Florida emphasizes our need for a continued high priority for our immunization programs.

The increased incidence of measles has received much attention in the last 2 years and has been discussed extensively this morning. Last year, more than 17,000 cases occurred nationwide, and recently the Public Health Service recommended that all children be routinely revaccinated with a second dose of the MMR vaccine. This will necessitate additional funds to implement the two-dose schedule. Many States are currently unable to initiate the two-dose schedule because of inadequate resources.

Last year, Florida experienced its highest number of measles cases since 1981. A total of 320 cases occurred in 23 counties. Fortunately, no deaths occurred but 30 percent of the persons who became ill developed at least one complication such as encephalitis, pneumonia and middle ear infections, often requiring hospitalization.

With 249 cases of measles so far this year, both the human suffering and the financial expenses necessary to contain the outbreaks continue. In January, Florida implemented the new outbreak recommendations released by CDC which call for revaccination of children in schools, child care centers and other institutions experiencing measles cases. Consequently, hundreds of thousands of vaccine dollars have been spent so far for outbreak control in 21 of our counties. These outbreaks are expected to continue until the new two-dose measles vaccination schedule is implemented as a routine.

Of particular concern is that almost one-third of Florida measles cases occur in unvaccinated preschool children. Most of these cases occurred in children who were more likely to receive their health care form the public sector and to live in a household with no employed adult. From a public health standpoint, most measles cases in preschool aged children are preventable. We need the resources provided through the National Immunization Program to be able to continue these efforts effectively.

It is also important to keep a substantive supply of vaccines stockpiled for smooth program operation under normal circumstances. During outbreaks sufficient stockpiling is essential. Vaccine must be supplied promptly to effectively contain spread of disease. Federal support of this effort is essential.

The seriousness of the vaccine-preventable diseases such as measles, rubella, polio, diphtheria and tetanus is well known. However, we must sustain our efforts to educate the public that these diseases are not totally eradicated and that immunization of all children is essential. The continued assistance from the Federal Government is vital to all of our vaccine-preventable disease control activities, from investigation of cases to vaccine provision to public education.

We ask your support for the reauthorization of the Federal Immunization Program. Thank you.

Mr. WAXMAN. Thank you very much, Dr. Witte.

Dr. Guerra.

STATEMENT OF FERNANDO A. GUERRA

Mr. GUERRA. Thank you, Mr. Chairman and members of the committee. It is a privilege for me to be with you this morning and to share with you the perspective of a local health officer.

I will speak from the framework that I know best, that of a local public health official charged with the day-to-day responsibility of preserving, protecting and enhancing the health of the citizens in our service area.

In addition, I have been a practicing pediatrician in San Antonio for over 20 years and most recently I have the honor of serving on the National Vaccine Advisory Committee. In this latter capacity I have the opportunity to review and evaluate national programs, policies and strategies that impact on vaccine preventable illness and translate them to the front lines, if you will.

This experience base has provided me with a unique point of view from which to address these concerns with you and members of your subcommittee. In addition, it allows me as a local health

officer to strongly state the case for recommending reauthorization with increased funding for the Childhood Immunization project.

Perhaps I can most effectively state this position by using my experience in San Antonio as a case history of sorts. San Antonio is one of only a handful of communities in this country which is directly supported and funded for its childhood immunization project through the Centers for Disease Control grant process. This developed out of a series of linkages that were forged in 1971 when our community faced a major outbreak of diphtheria.

The manpower, financial and technical support provided to us by the CDC Immunization Program in that crisis was invaluable. The relationships that were established have grown stronger over time and today we enjoy a very positive and very supportive relationship. In fact, we are currently doing a demonstration project for early childhood immunization efforts to try to effect those important considerations that perhaps will allow us to better serve the high risk or hard-to-reach populations.

It is easy for you to understand, perhaps, what a shortfall in funding to this overall project might mean to a community such as ours. For example, our metropolitan health district has provided in the past year over 75,000 immunizations to children zero to 5 years of age. Over 60 percent of our community's children entering school for the first time rely on the public sector to provide this vital service. Demand for these services has been increasing at the rate of 3 to 5 percent each year.

The immediate shortfall which we face this year of $300,000 translates to a 30 percent reduction in our ability to provide immunizations to this population. This means close to 23,000 fewer youngsters will receive these immunizations. There are no clearly defined options for us on the horizon to offset this reduction.

With the public sector facing increasing demands and our colleagues and fellow practitioners involved in delivering primary care citing skyrocketing costs of vaccines and their concern regarding liability issues as reasons for some of this shift from the private to the public sector, we will continue to have these kinds of increased demands for services in the future. This raises some important policy issues that are beyond the immediate scope of this hearing today. The implications for the public health field and particularly the local health departments and medical profession in general are profound.

We need to recognize that overall the public health care sector's campaign over the years for better compliance with immunization guidelines and levels has been remarkably successful. It is estimated that at least 95 percent of our population throughout the country is well protected. However, if we look at this data more carefully we become acutely aware of the significant gaps and lags in this coverage.

We recognize that in the lower socioeconomic groups, the recently arrived immigrants, especially those that are of undocumented status, the preschool and the under 2-year-old age groups continue to stand out in bold relief. Analysis has demonstrated that from 40 to 60 percent of these selected subgroups lack required immunizations.

Nationwide, we can continue to point with pride to the fact that we have in place school entry codes that prevent youngsters from enrolling in school without proof of immunizations. However, we must remember that children do not reach this crucial checkpoint until they are at least 4 years of age. Our own annual audits of birth records and day care enrollments in San Antonio indicate that perhaps 40 percent of the under 2-year-old population has either no immunizations or an incomplete series.

We can continue to take satisfaction from the fact that we have reached 95 percent of our goal in terms of overall immunizations. However, we must not lose sight of the fact that the remaining 5 percent truly represent a missed opportunity for our health care system to have reached out and touched those hard to reach.

These are families, especially the infants and children, who are not presently linked to our medical system. Such care as they receive quite often is fragmented as they rotate from clinic to hospital emergency room to other health care providers in the community. While the presenting or acute problem may be addressed and addressed quite well, we know that only cursory attention is paid to the status of immunization.

You can understand how the window for exposure and potential infection in a community such as ours, as in many communities around the country, is open more widely than just a crack. This at risk and vulnerable population must be recognized and be assigned the highest priority not only for its own sake, but to protect the larger community as well.

In the last 3 years our community has consistently led the State of Texas—and this in spite of major efforts to enhance immunization levels—in the number of pertussis cases and *Haemophilus influenza B* meningitis cases. In 1989, we confirmed 44 cases of pertussis, 24 cases of life threatening *Haemophilus* influenza meningitis, three cases of mumps, and 80 cases of measles. Followup by our staff epidemiologist revealed that a significant number of these cases were among families where the children had either not been immunized or had an incomplete series.

I would like to state clearly for you that along with other local communities across the country, that to maintain these current levels of immunization and begin to make significant inroads in these at risk subgroups, we must rely on the continued presence, support and effectiveness of the Childhood Immunization Program. We cannot slacken in this effort.

However, there are some nonfunding related issues that must be addressed as well. One of those has to do with the current status of the distribution network, and in particular those providers within that distribution network that perhaps are not always the best for the job.

In local health departments, we need to redouble our efforts to attract more adults into the immunization efforts because of the opportunity that this provides to continue to immunize children, especially those that are hard to reach.

Finally, I would only add my strong endorsement to the request to reestablish adequate levels of funding to the Childhood Immunization Program. Without additional funding, we will not be able to continue to enjoy the successes of recent years and will invariably

experience some slippage. Without a continued and sustained presence, our current efforts will lose momentum as well as the opportunity for new initiatives that must be launched. It is no longer the search for a magic bullet that concerns us here today. Biomedical research and technology has armed us with effective weapons in our public health arsenal. Rather, we are seeking the resolve and the resources to deliver well aimed shots at the hard-to-reach targets in our community.

Thank you. I will be pleased to answer your questions.

[The prepared statement of Mr. Guerra follows:]

TESTIMONY GIVEN BY:

Fernando A. Guerra, M.D., M.P.H.
Director of Health
San Antonio Metropolitan Health District

Mr. Chairman:

I appreciate having the opportunity to address you today on the critical issue of continued and increased support for the Childhood Immunization Project. My colleagues will offer testimony reflecting their own distinctive perspectives on the topic. I will speak from the framework I know best - that of a local public health official charged with the day to day responsibility of preserving, protecting and enhancing the health of the citizens in our service area. In addition, I have been a practicing pediatrician for over twenty (20) years and most recently I have had the honor of serving on the National Vaccine Advisory Committee. In this latter capacity, I have the opportunity to review and evaluate national programs, policies and strategies that impact on vaccine preventable illness. This experience base has provided me with a unique point of view from which to address these issues with you and members of the Subcommittee on Health and the Environment. In addition, it allows me, as a local health officer, to present my recommendation for re-authorization with increased funding for the Childhood Immunization Project.

Perhaps I can most effectively state my position as an advocate by using our experience in San Antonio as a case history of sorts. San Antonio is one of only a handful of communities nationwide that

is directly funded and supported for its Childhood Immunization Project through the Centers for Disease Control (CDC) grant process. This originally grew out of linkages that were forged in 1971 when the city was combating an epidemic of diphtheria. The manpower, financial, and technical support provided to us by CDC in that crisis was invaluable. The relationships that were established at that time grew stronger over the years and have been most effective in the current situation that supports our immunization program. Simply put, this financial and staff support from CDC represents the backbone of our current initiatives in the area of childhood immunization. In this context it is easy to understand what a shortfall in funding means to our community in terms of a significant lack of vaccine doses.

Let me offer a brief profile of our community so you can more fully appreciate the impact of a shortfall of $300,000 as our portion of this national dilemma, i.e. increased demand versus diminishing resources. Bexar County, with San Antonio as the county seat, is the 10th largest metropolitan area in the United States and has a population of over 1,179,000 people. It is situated in South Central Texas with a mostly urban population but with semi-rural and rural communities contributing to the county's growth, economy and daily life. The population make-up is 48% Mexican/American, 8% black and 44% white. In common with many communities in the

American Southwest, our minorities have come to represent our new majorities and this has presented us with new challenges as we attempt to re-cast our public health strategies. The annual 1985 per capita income was $8,499 with an unemployment rate of 6.1% as of January, 1990. Our Department, with its sixteen (16) public health clinics, maintains close working relationships with the three (3) federally funded urban health initiative clinics, eight community centers, the Bexar County Hospital District, and the University of Texas Health Science Center. In addition we have responsibility to assure adequate levels of immunization in sixteen (16) public school districts and a sizeable number of private institutions. These agencies provide health care and preventive health services for over 45% of the population. The remainder of the population utilizes the private health care sector. It is important to take note here of this heavy reliance on the public sector as it impacts directly on the issues that surround funding for childhood immunizations.

For example, the San Antonio Metropolitan Health District (SAMHD) has provided immunizations to over 75,000 children 0-5 years of age. Over 60% of our community's children entering school for the first time rely on us to provide this vital service. Demand has been increasing on an average of 3-5% each year. The immediate shortfall of $300,000 we are facing translates to a 30% reduction

in our ability to provide immunizations to this population. This means 22,594 fewer youngsters will receive these immunizations. There are no clearly defined options on the horizon to offset this reduction. The public sector has increasingly been forced to take the lead in offering these services. My colleagues and fellow practitioners involved in delivering primary care cite the skyrocketing cost of vaccine and their concern regarding liability issues as reasons for this dramatic shift to the public sector. Obviously this raises policy issues beyond the immediate scope of our testimony here today, but the implications for the public health field and the medical profession in general can be profound.

We need to recognize that overall the public health care sector's campaign over the years for better compliance with immunization guidelines and levels has been remarkably successful. It is estimated that at least 95% of our population is well protected. However, if we look more carefully at the data we became aware of significant gaps and lags in our coverage. The lower socio-economic groups, recently-arrived immigrants (as well as those with undocumented status), the preschool and the under two year old age groups stand out in bold relief. Analysis has demonstrated that from 40-60% of these selected subgroups lack required immunizations. Nationwide, we can point with pride to the fact that we have in place school entry codes that prevent

youngsters from enrolling without proof of immunizations. However, children don't pass this crucial checkpoint until they reach 5-6 years of age. Our own annual audits of birth records, day care enrollments, etc., indicate that perhaps 40% of the under two (2) year old population has either no immunizations or an incomplete series. If we take some satisfaction from the fact that we have reached 95% of our goal in terms of overall immunizations we must not lose sight of the fact that the remaining 5% represent a truly lost opportunity for our health care system to reach out and touch the "hard to reach". These are families, especially the infants and children, who are not presently linked to our medical system. Such care as they receive is fragmented as they rotate from clinic to hospital emergency room to other health care providers in the community. While the presenting or acute problem may be addressed, we know that only cursory attention is paid to the status of their immunization records. You can understand how the window for exposure and potential infection is open more than a crack. This "at risk" and vulnerable population must be recognized and be assigned the highest priority - not only for their sake but to protect the larger community as well. For example, prior to 1988 Bexar County had not had a major measles outbreak since 1985 when over 73 cases were reported. However, in the last three (3) years we have consistently led the State of Texas in the number of Pertussis cases, and Haemophilus influenza B meningitis. In 1989, we have confirmed the following: 44 cases of Pertussis, 24 cases

of life threatening Haemophilus influenza B meningitis, 3 cases of Mumps, and 80 cases of Measles. Follow-up by our staff epidemiologist revealed that a significant number of these cases were among families where the children had either not been immunized or had an incomplete series. Yet San Antonio does maintain an average of 95% age-appropriate rate of immunization in the day care, preschool and school age populations. Our priority concern continues and must continue to be directed to our newborn to preschool population, especially our 0-2 year old grouping. At the same time, we must obviously recognize that public health has the responsibility to provide protective immunity to adult and elderly populations as well.

In San Antonio we experience all of the normal constraints and impediments to the provision of adequate immunization services that any other large metropolitan city faces. In addition, we encounter special challenges! We are a bicultural community and derive a large degree of pleasure and pride from that fact. That reality, however, impacts on the health care delivery system in many different ways. Simple communication, let alone health promotion and education efforts is limited unless bilingual resources can be marshalled more effectively. Families who have only recently relocated from Mexico or Central America (and even 1st and 2nd generation residents) don't share or easily identify with many of our traditional notions of preventive medicine. Combine this with

our proximity to the border and the extensive two way traffic that generates and you have a potentially dangerous situation. Disease, especially infectious disease, does not respect borders be they national, state or those other less visible lines which attempt, to separate class, race or other social groupings.

If we, along with other local communities across the country, are to maintain these current levels of immunization and begin to make significant inroads into these "at risk" subgroups we must rely on the continued presence, support and effectiveness of the Childhood Immunization Project. This effort cannot slacken! However, other non-funding related issues need to be addressed as well. Our distribution network needs to be redesigned to assure that the vaccine we do have on hand finds its way through the most efficacious channels to those most in need. Medicaid, EPSDT and other public assistance programs should help lower the cost or reimburse physicians for vaccinations to these "at risk" populations. We should also look critically at the physicians involved in these programs and make certain that they are "the best for the job."

While working toward broader availability of these vaccines we must reach out to these groups in a more creative and innovative fashion. New relationships must be established which will allow

access and add credibility to our efforts. We have been effective to date with the schools and the media but it clearly has not been enough. We must identify and enlist the aid of a wider range of support from public and private sectors both within and outside the traditional community of health care providers.

Locally, we have seen the incidence of Hepatitis B increase by 75% over the past year, mainly in intravenous drug users and their sexual partners. Of special concern is the frequency of adolescent pregnancy among this "at risk" population. There is an effective vaccine which will prevent this very serious disease, but because of cost it is used in only a small fraction of cases. If funding were available for purchase of Hepatitis B vaccine, it could immediately be made available through existing clinics to persons "at risk". Expenditures on vaccine to prevent this disease would be realized many times over in lower hospital costs for acute and chronic care of hepatitis. However, funding for Hepatitis B should NOT be taken from the Childhood Immunization Project. It must be IN ADDITION to the funding for childhood vaccines.

We need to re-double our efforts to attract more adults into our present immunization initiatives. Through them, especially the parents, we have a unique opportunity to educate and involve the

children. We should look upon any situation where there is interaction with the health care community as an opportunity to be maximized.

In conclusion, I can only add my strong endorsement to the request to re-establish adequate levels of funding to the Childhood Immunization Project. Without additional funding, we will not continue to enjoy the successes of recent years and will invariably experience slippage. Without a continued and sustained presence, our current efforts will lose momentum, as well as, the opportunity for new initiatives that must be launched. It is no longer the search for a "magic bullet" that concerns us here today. Biomedical research and technology has armed us with effective weapons in our public health arsenal. Rather, we are seeking the resolve to deliver "well aimed shots" at the "hard to reach targets" in our community.

Mr. WAXMAN. Thank you very much for your testimony.

Each of you is on the "front line" both in trying to stop preventable childhood diseases in the first place and in dealing with these illnesses when outbreaks occur.

Would you please describe the health consequences that can occur when a child contracts diseases such as measles, childhood meningitis, or pertussis? Can these diseases be fatal among children?

Mr. WITTE. Absolutely. I mentioned earlier that we recently had a diphtheria death among an unimmunized child under 1 year of age in Florida. The death that occurs from the complications of measles occurs in about 1 in 1,000 cases. Other vaccine preventable diseases also lead to complications and death.

Mr. GUERRA. I would certainly add to that that it is not only the immediate life threatening situation that puts an infant or a child in a compromised state that ultimately leads to death. We must also be concerned about the long-term sequelae, the neuro-developmental kinds of residual impairments that quite often result because of the encephalopathies or the profound inflammation of the central nervous system.

Mr. WAXMAN. I know you can't give us exact figures, but give us some idea of the kind of costs that would be incurred in trying to treat some of these complications that could have been prevented had the children been immunized.

Mr. GUERRA. With my pediatrician's hat on, I would say that the immediate costs when a critically ill infant or child is admitted to an intensive care unit at perhaps a rate of close to $1,000 to $1,500 a day—especially when life support systems have to be put into use, over a period of maybe 8 to 10 days during the acute phase and then the convalescence—could be anywhere from $20,000 to $30,000, just for an acute illness. I know in recent years when we have managed some infants with whooping cough or pertussis during the course of their 3 to 4 week stay in the hospital, it is not unusual for the families or the insurance companies to be faced with costs in excess of $50,000.

Mr. WITTE. In addition to that, Mr. Chairman, we did a study a number of years ago on the costs and benefits of immunization and found that the indirect costs due to loss of productivity, particularly from neurologically impaired individuals over a lifetime, far exceeds the impressive medical care costs.

Mr. WAXMAN. In recent years both of you have had to deal with measles outbreak. In your State, Dr. Witte, you told us that in 1989 alone, Florida experienced a total of 320 cases spreading over 23 counties. Dr. Guerra, you said that for the same year, your county reported 80 cases of measles.

What do your numbers look like for 1990? Will the numbers be any better?

Mr. GUERRA. In Texas, certainly the numbers continue to increase. In our own community thus far this year we are now at about a level of 12 cases with one or two suspected cases that were called into our department earlier this week. In communities all around us the numbers have been even greater than that.

Mr. WITTE. To date this year, Mr. Chairman, we have recorded 249 confirmed measles cases in 21 counties. Traditionally, in Flori-

da, outbreaks continue until the end of the school year, and so we are just beginning.

Mr. GUERRA. I would add to that, Mr. Chairman, that in addition to those numbers that we face within our geographic area of responsibility, that through unofficial sources and reporting systems there has also been a major outbreak in Mexico. That certainly will be impacting across the border States in this country. The numbers presently range about 15,000 to 17,000 cases of measles within the last 2 to 3 months in Mexico.

Mr. WAXMAN. Have you been able to get all the Federal assistance you need to purchase vaccine through the Centers for Disease Control? Have you been able to get all the personnel assistance you need through CDC?

Mr. GUERRA. As it affects our local health department, it has been sort of an unpredictable kind of support in recent years. There have been times when we have been able to pretty much keep our efforts at a status quo.

In the past 6 months, there has been a situation where through the regional office the request has come down that we somehow need to be able to offset those reductions that they are not able to keep up with by looking to local sources or other means of supporting them. This has affected some staff positions for us and also the availability of some vaccine doses.

Mr. WITTE. In Florida, the Centers for Disease Control has been very generous in the amount of dollars they have sent to us. However, it has been necessary for our legislature to appropriate additional funds, and during outbreaks we have had to go into State emergency funds to provide the resources to contain them.

Mr. WAXMAN. Thank you very much.

Mr. Nielson.

Mr. NIELSON. Dr. Guerra, you mentioned some areas where there was a high percentage of individuals who do not get immunized. Can you explain why that is and what actions if any you are taking to relieve that situation, and finally, what the rate of disease outbreak is in that group as compared with the normal population?

Mr. GUERRA. I think it relates to a combination of circumstances. One that I would certainly like to highlight is that we have not always had the best match in terms of provider sources within either the public or private sector and the population that they are meant to be serving. I think that with the added situation that has resulted from the increased costs that providers are no longer able to keep the kind of vaccine inventory available within their clinics or their office practices. This further compromises the ultimate opportunity.

There is a situation within the Medicaid and the EPSDT Program, as an example. That has tremendous responsibility and on a regular basis interacts with the population that has been the hardest to reach.

Mr. NIELSON. What have you done to try to remedy the situation?

Mr. GUERRA. One of the things that we have tried to do is to identify those Medicaid and EPSDT providers that have within 25 to 30 percent of their practices a population of Medicaid recipients,

AFDC recipients, and to have provided them with vaccine at no cost provided that they maintain strict accountability and documentation and show us that they are immunizing that population that comes in.

Mr. NIELSON. Is there any rate of disease difference between the group that is not immunized and the group that is immunized? Do you have those figures and would you supply them for the record?

Mr. GUERRA. In the zero to 2 age group, the attack rate of those vaccine preventable conditions has consistently been higher in those from the disadvantaged backgrounds, from those sectors of the community that have not always been able to access it.

Mr. NIELSON. Would you provide some detail on that for the record?

Mr. GUERRA. Yes.

Mr. NIELSON. A previous witness talked about requiring entry for day care and preschool at 5 or 6 and they should have immunization records available and ready by that time before they enter those programs.

Do you agree with that?

Mr. GUERRA. Yes, sir.

Mr. NIELSON. Is 5 or 6 sometimes too late for the vaccination? If a child arrives ready to go to day care or preschool and hasn't had those done, has he sometimes missed the boat, and if so, what can you do about it?

Mr. GUERRA. They have certainly missed it and have remained at risk during those critical periods of their development.

In the child care ordinance that we have recently passed, we have included a section specifically addressing the requirement for basic immunization, including the *Haemophilus influenza B* meningitis vaccine, prior to entry into day care.

Mr. NIELSON. What would be a better age? You say 5 or 6 sometimes may miss some people. They have been at risk too long, particularly in the one you just mentioned. What is a better age to require it, and if so, how do you do it?

Mr. GUERRA. As hopefully there are more and more opportunities for children to go into early childhood programs, day care and child care programs, it should be required prior to entry at that time.

Mr. NIELSON. So at 3 or 4 maybe rather than 5 or 6?

Mr. GUERRA. That's correct.

Mr. NIELSON. Dr. Witte, what does Florida do to encourage immunization of children other than the CDC Program which you obviously participate in?

Mr. WITTE. We begin at the hospital or birthing center at the time a child is born, giving educational materials to the mother. It is followed up at 2 months of age with a mailing to all live births that occur in Florida. We survey children at 7 months of age to assure that they have begun their immunization series. We also survey children at 2 years of age when they should have completed the first round of immunization. We carry on an extensive Education Program and we have a very strict school entry requirement which allows only those with valid medical reasons or valid religious reasons to enter school without being fully immunized.

Mr. NIELSON. Do you charge an administration fee for the vaccines in your State?

Mr. WITTE. No, sir.

Mr. NIELSON. How about Texas? Do you charge an administration fee there?

Mr. GUERRA. It is basically an administration fee that is waived because of inability to pay.

Mr. NIELSON. What about immigrants coming to this country? Are they required to get immunized when they arrive under current laws?

Mr. WITTE. This is a very difficult problem. In Florida, we have people coming from Latin America and from the Caribbean. These are often people coming in medically indigent, with language problems, with social barriers, and many of these people are illegal aliens. So reaching them is exceedingly difficult. The immunization levels in these populations are very low.

Mr. GUERRA. Essentially we know that we are serving many who have recently arrived in our community through our immunization clinics. It has been very difficult to access their prior records of immunization and so essentially we start the whole process over.

Mr. NIELSON. I have one last question, Mr. Chairman, if I may.

Dr. Guerra, you made a very interesting statement. In San Antonio you experience all of the "normal constraints and impediments to the provision of adequate immunization services."

Would you elaborate either now or for the record what those normal constraints and impediments are and suggest how they can be overcome?

Mr. GUERRA. Yes, sir.

Mr. NIELSON. Would you do that for the record?

Mr. GUERRA. Yes, sir.

Mr. NIELSON. Thank you.

Mr. WAXMAN. Thank you, Mr. Nielson.

Dr. Rowland.

Mr. ROWLAND. Thank you, Mr. Chairman.

Both of you talked about the importance of vaccinating preschool children, these hard-to-reach children; that is, those in who you see the greatest number of diseases whether it be cases of measles, pertussis, meningitis or any of the other preventable childhood diseases. Are additional funds needed in order to find and vaccinate these children, and if so, does CDC provide adequate assistance in this type of effort?

Mr. WITTE. In answer to your first question, absolutely additional funds are needed to do outreach work, to find preschool children who are not being adequately protected. We do receive some support from CDC to do this but additional resources are necessary, at least in Florida.

Mr. GUERRA. I would certainly echo that. It is tremendously important within a local health department to be able to assign staff from other divisions to help with immunization efforts during special campaigns or times of need.

Mr. ROWLAND. Dr. Guerra, you stated that it may be more appropriate to vaccinate children at age 3 to 4. Isn't it true that the public health experts recommend that vaccines be administered

earlier than that? The recommendations for DPT, polio and measles are all for earlier ages?

Mr. GUERRA. I certainly agree with the recommendation for the earlier ages, but I think as one goes through a process of transition to try to at least maximize opportunities that if we find more and more children going into earlier childhood programs, to move up the requirement prior to entry into those programs, to the age of 3 to 4. Certainly that gives us a couple of years of additional benefit and protection rather than wait until they are 5 or 6.

I think that there has to be a totally separate initiative for the zero to 2, which is still the highest risk group. But I think in terms of points of entry where at least you can try to maximize an opportunity, it is important to catch those going into early childhood programs. Fortunately, we are seeing more and children benefit from that.

Mr. ROWLAND. What is the apparent incidence of vaccine failure in children say, for example, with measles?

Mr. WITTE. The early vaccine studies that were done at the time of licensure of measles vaccine showed that it was about 95 percent effective. We have no reason to believe that that has diminished over time. As Dr. Hinman explained earlier, the outbreaks that are occurring are not because of decline in protection. But that 5 percent susceptible in a closed population such as a school or day care center will allow the sustaining of an epidemic.

Mr. ROWLAND. Thank you.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Dr. Rowland.

Mr. Sikorski.

Mr. SIKORSKI. I have no questions. I want to thank the panelists for their help.

Mr. WAXMAN. Thank you both very much for your testimony. We appreciate your cooperation.

Appearing on our last panel and representing the American Academy of Pediatrics is Dr. Georges Peter. Dr. Peter is the director of the division of pediatrics and infectious diseases at Rhode Island Hospital in Providence, RI.

Thank you for being with us this morning. Your prepared statement will be in the record in full. We would like to ask you to limit your oral presentation to no more than 5 minutes.

STATEMENT OF GEORGES PETER, DIRECTOR, DIVISION OF PEDIATRICS AND INFECTIOUS DISEASES, RHODE ISLAND HOSPITAL, ON BEHALF OF AMERICAN ACADEMY OF PEDIATRICS

Mr. PETER. Thank you, Mr. Chairman. I would add also that I am a faculty member at Brown University and I serve also as the editor of the "Report of the Committee on Infectious Diseases of the American Academy of Pediatrics," commonly referred to as the "Redbook", which provides national recommendations for prevention of infectious diseases. And I am also a member of the National Vaccine Advisory Committee.

I will attempt to abbreviate my comments since many of the points that we view as extremely important have been well covered by my predecessors from the private and public sectors.

Without doubt, individual vaccines are effective in preventing disease and save our society enormous sums of money. However, success sometimes can breed complacency. Today, statistics, as we have heard, paint a distressing picture of our immunization programs, which indicate a failure to fulfill the potential made possible by the advances of medical science in the United States.

We have heard about increased number of cases of pertussis; we have heard about the marked increase in measles, and I would add to the roster of States that have experienced measles outbreaks for the first time in many years, Rhode Island. The last outbreak was in the late 1970's. Again we have had an outbreak in 1989.

Ms. Johnson discussed the Surgeon General's objective that by 1990, 90 percent of the Nation's children at age 2 years should be fully immunized. We have not met this goal and indeed the resources for so doing in terms of vaccines, medically speaking, are available and all children should be afforded the benefits of immunization at the recommended age. I certainly support her comments for increased resources to ensure that we do so.

Among the several reasons for this declining immunization rate—one of the important ones—is the increased cost of vaccines. In the private sector the increased cost of the vaccines has driven parents from their private pediatrician's offices to public clinics. In California, for example, the use of public health clinics for immunizations rose 30 percent in 1 year. We hear of reports from Minnesota that as many as 70 percent of childhood immunizations are now provided in the public sector. Hence the traditional 50–50 public-private partnership in the provision of childhood vaccines should be reexamined in this budgetary process.

Conservatively, we estimate that an additional 10 percent is needed in the immunization grants to States to assist in the purchase of the necessary vaccines to provide adequate support.

The lack of concrete data to clarify existing inadequacies and shortfalls in our Childhood Immunization Program is appalling. Of particular concern to the Academy of Pediatrics is the discontinuation in 1986 of the U.S. Immunization Survey. Hence, 1985 is the last year in which immunization rates were formally tabulated. In view of the relationship between immunization levels and the utilization of other preventive and medical services, such data becomes even more important in our efforts to ensure the health of all children.

From moneys appropriated this last fiscal year for the Infant Immunization Initiative, an immunization assessment now will be included as part of the health interview survey under the auspices of the National Center for Health Statistics. We call this to your attention for two reasons. First, so that funding for the survey is not lost in the appropriations process, and second, to highlight it as a cost-effective method of obtaining important health information.

A comprehensive surveillance system of age specific vaccine rates should be developed which details not only immunization rates, but also identifies the reasons children are not immunized at the desired age. The Infant Immunization Initiative of CDC should remain a high priority for funding to ensure better compliance with our Nation's recommended schedule of immunizations and national health objectives. The National Vaccine Advisory Committee

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has given its unqualified support to this program as an essential step in improving vaccine delivery, which I think is one of the major problems we have addressed this morning.

Another way to improve our immunization rates for the preschool population would be more effective coordination among the various Federal and State funded programs for children. To achieve this, proof of age-appropriate immunization should be required for WIC, day care, Head Start, the Early Intervention Program under the Education for Handicapped law, and the AFDC programs.

Additional issues are straining the limited resources of the Nation's Childhood Immunization Program. In particular, as we have heard so often this morning, the resurgence of measles.

We have discussed the new recommendations in this country, which the Academy supports, although there are differences in the age at which the second dose should be given. As you have so clearly noted, no moneys have been requested by the administration for the second dose.

I might add that the recommendations of the Academy for a second dose were made public last summer and I think should have been known to the administration and included in the budget.

A further point, too, is that with the occurrence of measles in innercities, the age of initial immunization has moved to less than 1 year of age, that is, 6 to 9 months of age, which then means that a child receives another dose at 15 months and then the third dose at school entry or entry into junior high school. This means three doses of vaccine for control of measles in this country.

The importance of funding for the *Haemophilus B* vaccine, the varicella vaccine, very likely, and the Perinatal Hepatitis B Program have already been duly noted. We certainly support and recognize the critical importance of these programs.

Given these new developments, increasing potential for prevention of disease and resulting changing recommendations for childhood immunization, we urge that rather than specify specific amounts of authorized dollars in the law, language be inserted authorizing "such sums as necessary." This would give the program the flexibility to help ensure age-appropriate immunizations for all children.

I was also going to mention the importance of the vaccine stockpile.

[The prepared statement of Mr. Peter follows:]

STATEMENT OF AMERICAN ACADEMY OF PEDIATRICS

Mr. Chairman, I am Georges Peter, M.D., Director of the Division of Pediatric Infectious diseases at Rhode Island Hospital, here today representing the American Academy of Pediatrics. I also serve as Editor of the Academy's Report of the Committee on Infectious Diseases, often referred to as the "Redbook."

The childhood immunization program is the cornerstone of preventive health care for many children in the United States. The program, a cooperative effort between the federal and state government, plays a vital role in ensuring that infectious childhood diseases no longer cause lifelong disabilities or death.

There is no doubt that the individual vaccines are effective in preventing disease, and they save money. Within five years of licensing the measles vaccine, reported cases declined 95%. The incidence of whooping cough (pertussis) fell to one-hundredth of prevaccination levels within 10 years after immunization began. In 1965, the reported incidence of paralytic poliomyelitis was 1/2 of 1% of the rate in 1955 when the vaccine first became available.

Success sometimes breeds complacency. Today, statistics paint a shameful picture of our immunization program. Pertussis or whooping cough is up 17%, with rates highest in

children under one year of age. Outbreaks of disease were highest in the states of Idaho, Kansas, Delaware and Hawaii. During the first 26 weeks of 1989, this country experienced a 380% increase in measles cases. States hardest hit included Texas, California, Ohio and Illinois.

The Surgeon General of the United States has established the objective that by 1990, 90% of the nation's children should be fully immunized. Yet the reality of the situation is that immunization rates are declining in this country; and they are lower than the immunization rates in many other countries. While our immunization rates at school entry remain on the high side, we are not doing nearly as well with our pre-school population.

There are several reasons for this declining immunization rate, but one of the major reasons is the increased cost of the vaccines. In the private sector, the increased cost of the vaccines has driven parents from their private pediatricians' offices to the public clinics. In California, for example, the use of public health clinics for immunizations rose 30% from the first quarter of 1988 to the first quarter of 1989.

Informal reports from Minnesota indicate that as many as 70% of the childhood immunizations are provided in the public sector. Similar anecdotal reports have been echoed by other

communities in various states. Hence, the traditional 50-50 public/private partnership in the provision of childhood vaccines should be re-examined for budgetary purposes. Conservatively, we estimate that an additional 10% is needed in the immunization grants to states to assist in the purchase of these "extra" vaccines.

Concurrently, to assure that the public clinics are meeting the demand for immunizations, additional state operation monies will be needed to facilitate expansion of clinic hours with appropriate staffing. Given the recent outbreaks of disease, more attention also needs to be invested in outbreak control.

The lack of concrete data needed to clarify existing inadequacies and shortfalls in our childhood immunization program is appalling. Of particular concern to the Academy was the discontinuation of the U.S. Immunization Survey in 1986. 1985 is the last year in which actual immunization rates were tabulated. Since there exists an important relationship between immunization levels and the utilization of other medical services, such data become even more important.

Through monies appropriated this last fiscal year for the Infant Immunization Initiative, an immunization assessment is to be included as part of the Health Interview Survey under

the purview of the National Center for Health Statistics. We call this to your attention for two reasons: one, so funding for the Survey is not "lost" in the appropriations process; and two, to highlight it as a cost efficient method of obtaining this important information.

A comprehensive surveillance system of age-specific vaccination rates should be developed which details not only immunization rates but the reasons children were not immunized. The Infant Immunization Initiative program of CDC should remain a high priority for funding to help assure better compliance with our recommended schedule of immunizations.

Another way to improve our immunization rates for the pre-school population would be more effective coordination among a variety federal/state funded programs for children. To achieve this, proof of age-appropriate immunizations should be required for WIC, child care, headstart, the early intervention programs under the Education for the Handicapped law, and AFDC.

There are several additional issues that are placing strains on the limited resources of the childhood immunization program. Official policy of the U.S. Centers for Disease Control, effective January, 1990, recommends a second dose of measles, mumps and rubella vaccine (MMR). No money has been

requested to cover the cost of this second dose in the FY 90 budget. It would take an additional $48.3 million to cover a second dose of vaccine for children at school entry and for those entering college. While these represent specific age groups the easiest points of proof of immunization, all those in grades 2 - 12 would have a long time waiting. The Academy's own policy recommends the second dose just prior to the Junior High level. In addition, the measles outbreaks across the country make earlier vaccination necessary for the first dose. Infants falling into this category will require 3 doses of MMR.

Hemophilus influenza type B vaccine, also know as HiB vaccine is now available. This prevents the most common cause of bacterial meningitis in young children. Some states are considering adding it to their list of immunizations required for school admission. As this is becoming standard practice, HiB vaccine should be added to the list of vaccines under the immunization program. While at present only 1 dose is required, an improved vaccine for younger-aged children is pending FDA approval. At that time, a 3-dose regimen will be necessary.

Also on the immediate horizon is approval of the varicella vaccine which will protect children from chicken pox. Attention will also be directed at fully implementing the perinatal hepatitis B program.

Given these new recommendations for childhood vaccines, we recommend that, rather than specify specific amounts of dollars in the authorization level, language be inserted indicating "such sums as necessary." This would give the program the flexibility to help insure access for all children to age appropriate immunizations.

The last component of the childhood immunization program which I want to bring to your attention is the vaccine stockpile. It is critical for the CDC to have a six-month supply of each of the vaccines on hand to meet any and all emergencies. Sufficient vaccines must be available to manage outbreaks of disease. Since 1983, we have had to dip into our stockpile on at least 5 different occasions.

Within its limited reach, the childhood immunization program is effective. But, due to fiscal constraints, the program is not reaching all children who need its protection. If immunization rates continue to decline, we will see increased rates of preventable diseases. The cost of treating and rehabilitating, or providing chronic care to, the children who survive and the costs associated with the deaths of children who do not survive far exceed the costs of this program. A study by the Institute of Medicine demonstrates that for every dollar spent on immunizations, $10 is saved. Increased authorization levels are needed to insure the following: that no child is denied immunizations; that new vaccines and recommended doses can be easily incorporated into the program; that vaccine stockpiles are maintained at a six-month level; and that annual records be kept of immunization status. As difficult as budgetary choices will be in the future, the reauthorization of this critical program should not inadvertently shortchange the needs of children in the years to come.

Mr. WAXMAN. Let me ask you some questions. I was going to get to that and whatever you didn't deliver in your oral presentation, we will certainly have in the record.

I was going to ask you about the stockpile of vaccines, especially the measles vaccine. Had we had it available in the stockpile, do you think that we might have been able to avert some of the outbreaks that many of the States have experienced?

Mr. PETER. No, I do not. I think where the stockpile problem is most highlighted is with respect to the DTP crisis that took place in the mid-1980's. I think the problem with the outbreaks of measles has not been inadequate supply of the vaccine, but rather inadequate delivery of the vaccine and also a need for a new program.

Mr. WAXMAN. You said that the CDC recommendation on the second measles shot will make children in grades 2 through 12 wait a long time. Do you believe that the CDC recommendation is adequate to address the measles problem in the United States, or is the CDC decision motivated by budgets? Do you believe we should be doing more?

Mr. PETER. I think the CDC's recommendation for school entry is based upon the ease of implementation. In other words, at the time of entry to school we have laws in effect which can require a second dose.

I think if one looks at the epidemiology of the disease and one wants to invest moneys to most rapidly reduce the incidence of measles, the time to reimmunize is entry into seventh grade. The outbreaks are occurring in school age population, primarily in junior and senior high schools and on college campuses. Therefore, by immunizing at the time of entry to grade school and at college entry, those children in high school will remain susceptible until 10 years from now when they reach that age.

Mr. WAXMAN. Would you do three shots or two and the second at a different time?

Mr. PETER. No. I think both groups agree that two doses are needed, a 15-month routine dose in the absence of an outbreak and then a second dose at entry to junior high school. Again, we would identify those entering college who didn't receive the dose at entry to junior high school for reimmunization. We do not advocate a third dose except in the case of an infant whose initial dose was given at less than 12 months of age.

Mr. WAXMAN. In your testimony you suggested that the increased cost of vaccines in the private sector are driving parents from their private pediatrician's offices to the public clinics. You cite California and Minnesota as examples where there has been a significant increase in the number of immunizations provided through public programs.

What is the difference in price of a complete schedule of immunizations between the private and the public sectors?

Mr. PETER. Mr. Waxman, I don't have that information at my fingertips. We can provide you that information. I actually have it in my file a listing of prices. We can certainly Xerox that. The differences are significant in the cost differential between the private and the public sector. The figure that I remember from last year when we were discussing the cost of reimmunization was approxi-

mately an $11 difference in the cost of MMR between the pubic and private sector.

Mr. WAXMAN. What evidence do you have that this increase in the number of children using public clinics is due to a shift from the use of private to public sector providers?

Mr. PETER. The information has been provided by State health departments. We can provide you with further data.

Mr. WAXMAN. Are we talking about moderate and high income families using the public sector clinics or are we talking primarily about lower income families or families with no health insurance?

Mr. PETER. I'm sure it relates to children with no health insurance. The cost of immunizing a child appropriately by the time of school entry now is well over $100. For an affluent family this is not a problem, but for many, many children, this is a significant cost.

I might add there are considerable differences throughout this country. For example, in the State of Rhode Island and four other New England States, all immunizations—irrespective of means—are provided by public sector funds whether a physician is in a public health center or is in a private doctor's office. In the other States the vaccines are primarily provided by Federal dollars for those who come to public clinics.

Mr. WAXMAN. Thank you.

Mr. Nielson.

Mr. NIELSON. I am impressed with your testimony, Dr. Peter.

The administration has asked for $131 million; Ms. Johnson suggested $250 million; the chairman is prepared to enter a bill somewhere in between there, nearer Dr. Johnson's figure.

If you had the following things, how would you prioritize them?

First of all, the vaccine stockpile.

The National Vaccine Program.

The second dose of measles.

The hepatitis B vaccine for pregnant women and newborns.

And the increased State operations money.

How would you prioritize those if we couldn't give you all of those things?

Mr. PETER. Mind you, you cannot field a baseball team without nine players. So you are asking me how I would establish the lineup.

Mr. NIELSON. You are only allowed seven in this game. How would you prioritize them? We can shoot for nine but we only have four in so far and we might have to reach a bit to get nine.

Which is the most important of these programs?

Mr. PETER. At this particular point in time, given the occurrence of the disease, to me the single most important program is the measles reimmunization.

Mr. NIELSON. The second shot of measles?

Mr. PETER. The second shot of measles.

Mr. NIELSON. What about the other ones, hepatitis for women and infants and also the State operations money?

Mr. PETER. I think the State operations money is critical to ensuring that children receive the other vaccines.

Mr. NIELSON. That is more important than the hepatitis?

Mr. PETER. From a public health perspective, in terms of dollars spent, yes. But I would not in any way want to say that I don't consider that important.

Mr. NIELSON. I am not asking which of your children you like best. I know I can't do that.

Let me ask the other part. How serious is our vaccine stockpile problem? Is that less serious than the hepatitis B for women and infants?

Mr. PETER. The Vaccine Stockpile Program in general is important. It is much like a life insurance policy. It is not important until you have a problem. This country now, for example, is dependent upon a single manufacturer for some vaccines.

Mr. NIELSON. If you had to choose between $10 million for that versus $10 million for hepatitis B for pregnant women and infants, which would you pick?

Mr. PETER. My personal view—and I am speaking personally now—is I would support the Hepatitis B Program.

I might add too, sir, that if one were to examine the epidemiology of hepatitis B and the fact that hepatitis B as a disease has increased in incidence rather than decreased since the availability of hepatitis B vaccine, we need to take a very serious look at our current strategies, and indeed if we are going to eliminate hepatitis B, we may need to have immunization in childhood.

Mr. NIELSON. I ask these questions simply because if we are able to pass Mr. Waxman's bill here and the Senate does not do as well as far as money is concerned and we have to go to conference, we would kind of like an idea of which is the most important in that case. I don't know if the chairman appreciates my line of questioning or not, but I think it might be helpful to us.

We talked about requiring immunizations for children as they enter day care and preschool, and that is age 5 or 6. Dr. Guerra thought that was too old, that they would miss a lot of them. I had suggested we ought to have some kind of mark point between, 3 or 4 or maybe earlier. Mr. Sikorski or Dr. Rowland had suggested even earlier than that.

How would you get an earlier period? The day care and the preschool you have everybody coming or most of them coming. You have a place to check them. How do you check them before that?

Mr. PETER. It is a very difficult question, because we do have school immunization laws that affect all children going to school. We have no similar mechanism.

Mr. NIELSON. You could apply that to day care or preschool as well.

Mr. PETER. Yes.

Mr. NIELSON. What else do we have before that?

Mr. PETER. What we need to do is ensure that children are immunized in the first year of life. After all, appropriate pertussis immunization requires initiation at 2 months of age. We have no mechanism in place. I think we need to develop such a mechanism.

Mr. NIELSON. And the meningitis to be effective has to be before age 2 at least.

Mr. PETER. At 2 months of age. We need to develop innovative strategies. I think one of the very important and critical programs currently in development now is the Infant Immunization Initia-

tive of the CDC which will identify, hopefully, the factors that lead to lack of age-specific immunization in children under 1 year of age.

Mr. NIELSON. Why do some children die from the medical treatment for measles? Why does the actual immunization cause death?

Mr. PETER. The immunization doesn't cause death. From measles vaccine?

Mr. NIELSON. The medical treatment for measles.

Mr. PETER. In other words, if you develop measles?

Mr. NIELSON. Yes.

Mr. PETER. The single most important factor about measles is that it is a neurotropic virus that can affect the brain. The other is that it can cause pneumonia. Approximately 1 in 1,000 to 1 in 2,000 children who develop measles will develop inflammation of the brain and about one-third of those will die and about one-third of those will have brain damage. Some of those children in addition who have measles may develop severe pneumonia.

I don't think you can measure the total morbidity and mortality and severity of measles simply by death. You have to look at the overall costs in terms of brain damage and suffering.

Mr. NIELSON. One last question. What happens to an infant born of a mother who has hepatitis B?

Mr. PETER. The infant has a chance of between 30 and 90 percent of developing a chronic lifelong hepatitis B infection. That infection is usually not manifest with symptoms in the first year of life but manifests itself in a lifelong increased risk of hepatic carcinoma and cirrhosis of the liver. In those countries in the world where hepatitis B is endemic, the leading cause of malignancy is indeed hepatic cancer and hepatitis B is a major public health problem.

So the measure of prevention of hepatitis B is really measured in terms of mortality in adulthood.

Mr. NIELSON. Thank you.

Mr. WAXMAN. Thank you very much, Mr. Nielson.

Dr. Peter, we appreciate your testimony and look forward to working with you.

Mr. PETER. Could I make one closing remark, sir?

Mr. WAXMAN. Certainly.

Mr. PETER. I would like to congratulate you, Mr. Waxman, on your efforts in support of the Immunization Program, particularly in support of the National Vaccine Injury Compensation Act which we hope will be successful in addressing some of these problems. We look forward to helping you in any way we can, you and your colleagues.

Mr. WAXMAN. Thank you very much.

This committee has also supported the Childhood Immunization Program. It has been a bipartisan matter and we have always worked together because the investment we make in preventing these diseases is a better investment than having to put money into treating children who develop these diseases.

Thank you very much.

[Whereupon at 12:01 p.m the subcommittee was adjourned.]

[The following material was received:]

Congress of the United States
Washington, DC 20515

Testimony of Congressman Craig A. Washington

Energy and Commerce Subcommittee on Health and the Environment

Reauthorization of the Federal Immunization Program

Mr. Chairman and Members, thank you for allowing me to express my views:

The increase in vaccine-preventable diseases across the Nation, specifically measles, requires a swift response. The problems faced by my constituents parallel the nation's predicament and Houston's measles epidemic is an example of the problem.

The primary case of a Houston area measles epidemic occurred in October of 1988. Cases did not stop accumulating until a total of 1776 cases had been reached in September of 1989. Prior to 1988 Houston traditionally reported between 5 and 30 cases of measles per year.

Seventy percent of the cases were preventable. In other words over half of the people who contracted measles should have already had their measles vaccination at the age of 15 months

but for some reason these children had not received the shot. In addition, 53% of the cases occurred in children less than school age.

Similar to other areas around the nation, the pool of children susceptible to measles had been accumulating in our pre-school age population for quite some period of time - such that when the first case of measles was introduced into the population the viral infection did not stop upon infecting one person, but spread rapidly into these groups of children who should have had their shots already.

Finally, Houston's measles epidemic, like similar outbreaks around the nation, did contain cases that occurred in the school-age population.

The majority of the measles cases are occurring in unvaccinated pre-school age children who utilize the public health system and live in the inner-city. The FY 91 budget is allocating roughly $8 million for special projects that would explore methods to reach these children. I applaud this action and look forward to the innovative programs that will result.

Remaining cases are occurring in school-aged children due to vaccine failure.

To combat the occurrence of measles in school populations, new recommendations have been made by the Advisory Committee On Immunization Practices. The first dose of vaccine will continue to be given at 15 months of age. The recommendations call for a second dose of vaccine to be administered to all children upon entrance to school.

In the case of low-income parents you often find that the child may only get the second dose because the parent may not have access to a physician who will administer the first does of vaccine at 15 months.

Cost estimates for this second dose are approximately $48 million and historically, the public system provides vaccine to half of the population of children requiring vaccinations. The cost for the children of low-income families to receive the second dose would require $24 million for vaccine. If the funding for the $24 million were to be provided by the traditional method, states would pay roughly $12 million with the FY 91 immunization grant program budget providing the remaining $12 million.

This money is not in the budget. States need the resources provided by the Immunization Grant Program if we are going to provide a second dose of vaccine to school-age children.

Several states, chief among them New York, California, Illinois, Florida and Texas, have special problems with the prevention of communicable disease such as measles.

The low-vaccine levels in these states have built-up over a period of time until we have what you see now - the rapid spread of a viral disease in a huge susceptible population.

States attempting to battle measles outbreaks while at the same time shoring up low-vaccine levels have a double burden on their resources. I would like to see these areas receive a grant allocation in proportion to the incidence of disease in the area.

To deal with outbreaks the FY 1991 budget has set aside approximately $10 million for outbreak control. This emergency fund is needed. In addition, areas of increased disease incidence need additional funding to provide a full slate of year-round immunization activities.

The allocation of $10 million for emergencies is a one-time solution to a problem that requires full-time attention and on-going activities.

I believe that, as in the case of Houston, if national efforts to immunize children had been diligently and stringently enforced and supported with adequate funding rather than funding that supported the purchase of the same doses of vaccine from 1987 to 1990, we would not have the measles outbreaks that we now see in at least ten states.

The Houston area experienced one of the worst measles outbreaks in the United States resulting in at least nine deaths. Yet their immunizations grant request, like many such requests around the United States was denied. Houston received $1.4 million of the $2 million requested.

Due to the increased efforts by the City of Houston to immunize more children, together with the increase in the number of children looking to the public sector for immunizations, Houston has indicated that their vaccine stockpile will be depleted prior to receiving their FY 91 grant allocation.

Where will they get extra doses of vaccine? It cannot be taken out of the $10 million dollar pool because that is for outbreaks. Continuous efforts in areas that have an increased incidence of measles, such as Houston, are critical if we are to prevent them from having to draw on that $10 million allocation which is set aside for outbreaks.

A simple truth, Mr. Chairman and Members: a grant allocation in proportion to need and ample enough to allow for everyday immunization activities, would prevent the nation from having to have a fund for emergency outbreaks.

In closing, I would like to commend the Federal Immunization Program for its fine work in preventing the spread of communicable diseases since 1962. Please take notice that, since the rise in measles in 1986 the funding levels for this program have not increased in proportion to the need for vaccine to halt and eliminate measles in the United States. States facing a multi-faceted battle - that of fighting on-going disease flare-ups, increasing low-vaccine levels with on-going programs and administering a second dose of measles vaccine - deserve a grant allocation in proportion to their need.

Allocations in the FY 91 budget for $8 million to fund projects to reach pre-school age children and $10 million to fight outbreaks are a wonderful beginning upon which to build intense, continuous efforts.

Mr. Chairman and Members, I support the reauthorization of the Federal Immunization Program. We must do more. We must allocate more. We mustn't be penny wise and pound foolish.

Thank you, Mr. Chairman and Members.

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS
6728 Old McLean Village Drive, McLean, Virginia 22101
Phone (703) 556-9222

March 9, 1990

The Honorable Henry Waxman
Chairman
Subcommittee on Health and the Environment
2415 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Waxman:

On behalf of the Association of State and Territorial Health Officials (ASTHO), I am writing to register our enthusiastic support of H.R. 4097 to reauthorize the tuberculosis control program within the Centers for Disease Control.

The Strategic Plan for the Elimination of Tuberculosis, which recommended that the United States set a goal for the elimination of tuberculosis by the year 2010, is not only a humanitarian but also a cost savings approach to this disease. ASTHO strongly supports this goal and the $36 million authorization for the Tuberculosis control program that is needed to help eliminate this deadly disease.

ASTHO commends you for taking the lead in this important area through introduction of reauthorization legislation.

Sincerely yours,

George K. Degnon, CAE
Executive Director

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February 22, 1990

The Honorable Henry A. Waxman
Subcommittee on Health
and the Environment
Committee on Energy and Commerce
U.S. House of Representatives
2415 Rayburn House Office Building
Washington, D.C. 20515-6118

Dear Mr. Chairman:

I would like to thank you and your colleagues for the opportunity to testify before the Subcommittee concerning the regimen of aerosol pentamidine for the prevention of Pneumocystis carinii pneumonia (PCP) developed by Memorial Sloan-Kettering Cancer Center and Fisons Corporation. The hearing on February 7 presented a strong case that the Orphan Drug Act should not be permitted to deprive people with AIDS of access to this beneficial new therapy.

The purpose of this letter is to address in more detail some of the concerns expressed by Committee Members and staff and specifically to respond to certain assertions by Mr. Brian Tambi of Lyphomed, Inc. As you know, Lyphomed is the company which holds Orphan Drug Act exclusivity for an alternative regimen of aerosol pentamidine for PCP prophylaxis. Mr. Tambi, in testimony before the Subcommittee as well as in other contexts, has questioned the relative merits of the Fisons system in a variety of ways. We believe the following information demonstrates conclusively that there is no basis for the claims asserted by Lyphomed and that the Orphan Drug Act should not preclude consideration by the Food and Drug Administration of the very different regimen developed by Sloan-Kettering and Fisons.

1. Cost-Effectiveness: Lyphomed claims that its system costs less than the Fisons regimen. This assertion, as the chart attached at Attachment 1 makes clear, is groundless.

The Fisons system costs substantially less for two straightforward reasons. First, due to the efficiency of its nebulizer, the Fisons regimen requires only a fraction of the drug required by the Lyphomed system. Using the current average wholesale price for Lyphomed's pentamidine, the monthly drug cost for the Lyphomed system is $99.45, compared to only $40 for the Fisons regimen.

Second, in addition to requiring less drug, the Fisons system is less costly to operate. The Fisons system is self-administered -- there is thus no need to incur the cost, at approximately $50 per treatment, of a respiratory therapist or other health professional. Similarly, because Fisons has developed, and patented, a premixed, unit dose solution for use in its system, patients treated with the Fisons regimen do not have to pay the pharmacist's preparation charge (for reconstituting the drug) of $5 per treatment associated with the Lyphomed system. Finally, because the Fisons nebulizer is reusable, patients on our regimen are not required to incur the monthly supply costs -- totaling nearly $10 per treatment -- that persons using the Lyphomed system must bear.

Lyphomed attempts to cloud the clear implications of these data by claiming that the nebulizer employed in the Fisons regimen represents a "hidden" cost that negates any savings achieved through more efficient use of the drug. This charge is untrue. The suggested retail price of the Fisons nebulizer when prescribed for PCP prophylaxis will be $200. Even when this onetime cost is included in the cost calculation, as it is in the attached chart, the Fisons regimen is still considerably less expensive than the Lyphomed system. The first, and more expensive, year of Fisons therapy is expected to cost $760, compared to $2,084 for the Lyphomed version.

The bottom line is that the annual cost of the Fisons regimen is less than half that associated with the Lyphomed system.

2. Safety and Effectiveness: Lyphomed also challenged the ability of the Fisons regimen to deliver therapeutic benefits comparable to those provided by its system. Such questions of safety and effectiveness are more properly addressed by the Food and Drug Administration, and I will not attempt a detailed refutation of Lyphomed's charges here.

Fisons, however, is confident that our clinical data firmly support approval of our regimen. Moreover, published, peer-reviewed literature prepared by independent scientists corroborates the effectiveness of the Fisons system.[1] A study commissioned by the National Institutes of Health found that the Fisons device delivered a greater percentage of pentamidine to the lung than the device used in the Lyphomed system. Other researchers have confirmed that the particles of drug created by the Fisons nebulizer are well within the range of particle size necessary for delivering medication to patients' lungs.[2]

1. Smaldone, G.C. et al, Journal of Aerosol Medicine 1988; 1 (2): 113-126
2. Stahlhofen, W., Gebhart, J., and Heyder, J.(1980). Experimental Determination of the Regional Deposition of Aerosol Particles in the Human Respiratory Tract. Am.Ind.Hyg Assoc.J. 41, 385-398.

In contrast, Lyphomed relies on reports prepared by a paid consultant, Dr. Bruce Montgomery.

3. Timing and the Equities: Researchers at Memorial Sloan-Kettering Cancer Center were the first to report on the use of aerosol pentamidine to prevent PCP in persons with AIDS. Significantly, that institution rejected overtures by Lyphomed, and opted instead to work with Fisons to develop its aerosol pentamidine regimen. Sloan-Kettering's decision was influenced both by Fisons' significant experience in developing nebulizer technology, and by this company's ability to perform the rigorous preclinical and clinical studies typically required by FDA.

The chronology attached at Attachment 2 demonstrates that Sloan-Kettering and Fisons were pioneers in virtually every step of the development of aerosol pentamidine. Indeed, the only step at which Fisons fell behind Lyphomed was FDA approval -- and we would argue that the reason Lyphomed won this "race" was because it was subject to a different set of rules. Fisons, following the express advice of FDA, conducted two properly designed and well controlled multicenter, double-blind trials, one placebo-controlled and the other low dose controlled. Prior to the completion of these trials, Lyphomed submitted data from a single, unblinded dose-response study -- data which FDA, in a marked departure from its previous advice to Fisons, found sufficient for approval.

While Fisons does not question FDA's finding that the Lyphomed system is safe and effective, we do dispute any claim by Lyphomed that, having "won" the race, it is entitled to marketing exclusivity. Surely the circumstances presented here do not represent the clear-cut victory anticipated by the Act.

4. Research and Development Efforts: Lyphomed contends that it has spent substantially more than Fisons to develop aerosol pentamidine. We, of course, have no direct knowledge of Lyphomed's expenditures. On their face, however, Lyphomed's claims are implausible, especially when the research and development efforts of the two companies are compared:

> Fisons' New Drug Application (NDA) is based on extensive preclinical and clinical testing. In contrast, Lyphomed's NDA consisted primarily of a single dose-response study.
>
> Fisons has developed a compact, portable, "user friendly" nebulizer. In contrast, Lyphomed relies on a relatively primitive system of heavy compressors and cumbersome tubing already found in most institutional settings.
>
> Fisons has developed a pre-mixed, unit-dose ampule of pentamidine. This work is so innovative it has been awarded a patent. In contrast, Lyphomed continues to rely on a powdered form of the drug which must be reconstituted before each and every treatment, requiring the use of a syringe and sterile water. This dosage form is essentially unchanged from

that which was available before Lyphomed ever became involved with the drug. In fact, since its initial involvement with pentamidine in 1984, Lyphomed has made no apparent improvements to either the drug or its dosage form. Similarly, Lyphomed has contributed no tangible improvements in the regimen for aerosol administration of pentamidine during the period of its involvement with that concept.

This is not the record of a company committed to research and development. On the contrary, it is Fisons, not Lyphomed, which has demonstrated a continuing and consistent commitment to improving the delivery of aerosol pentamidine.

* * *

The foregoing discussion, combined with our previous submissions, demonstrates that permitting the Fisons regimen on the market is both scientifically justified and, equally important under the circumstances, eminently fair. In closing, we note that Lyphomed has apparently suggested that it might discontinue research it is conducting on a completely different rare disease if it should lose its exclusivity for aerosol pentamidine. Obviously, the Subcommittee should not succumb to this threat. The Orphan Drug Act was never intended to finance a manufacturers' entire research and development effort. It is designed instead to promote research on a specific disease. Fisons has undertaken such research, and people with AIDS should not be precluded from reaping the benefits of our efforts.

Fisons is proud to have developed, in partnership with Sloan-Kettering, an important new therapy for those at risk for PCP. The Orphan Drug Act should not pose an artificial bar to a product such as ours, which employs a different dosage and nebulizer device than its competitor. We hope to continue to work with the Subcommittee to reconcile the admirable goals of the Orphan Drug Act with the needs of patients who could benefit from this therapy.

Sincerely,

Richard A. Foulds, M.B. M.R.C.P.
Vice President, Medical Affairs
Fisons Corporation

Attachments

ATTACHMENT 1

COMPARISON OF ANNUAL TREATMENT COSTS

	LYPHOMED Hospital/Clinic Use	FISONS Home Use
Drug[1]	$ 99.45/month $1,193.40/year	$120 -- 1st month $ 40 -- months 2-12 $560/year 1 $480/year 2
Nebulizer and Supplies	$ 19.27/month[2] $ 231.24/year	$200 -- one-time purchase
Respiratory Therapist	$ 50/month $ 600/year	Not Required
Pharmacist Compounding Fee	$ 5/month $ 60/year	Not Required
Total Annual Cost	$2,084.24	$760 -- Year 1 $569 -- Subsequent Years

1 Drug costs are based on Lyphomed's current average wholesale price. They do not include retail mark-up or pharmacist's dispensing fee.

2 Includes cost of compressor ($10/month).

ATTACHMENT 2

Aerosol Pentamidine Chronology

1983 CDC and FDA solicit companies to manufacture pentamidine for injection to be used in the treatment of Pneumocystis carinii pneumonia (PCP) as the supply dwindles because of greater incidence in people with AIDS.

1984 New drug application submitted by Lyphomed, a generic drug manufacturing company, using data collected by the CDC. Lyphomed receives seven years of exclusivity -- until 1991 - under the Orphan Drug Act for the injectable form of pentamidine as treatment for PCP.

1984 First published reference to use of aerosol pentamidine as prophylaxis for PCP by Dr. Armstrong and Ed Bernard of Memorial Sloan-Kettering Cancer Center. Sloan-Kettering receives NIH grant to expand preclinical studies of aerosol pentamidine prophylaxis.

1985 First human studies of aerosol pentamidine as prophylaxis for PCP initiated at Sloan-Kettering.

1985 Lyphomed approaches Sloan-Kettering to seek joint development of aerosol pentamidine , but Sloan-Kettering declines because of Lyphomed's inadequate nebulizer technology and lack of resources to perform preclinical and clinical trials required by FDA.

1986 Approached by Fisons, Sloan-Kettering agrees to joint development with that corporation, which specializes in nebulizer technology.

1987 At urging of Sloan-Kettering, Fisons requests orphan drug designation for aerosol pentamidine as prophylaxis. Orphan drug status approved for Fisons.

1987 Upon learning of Fisons orphan drug designation for aerosol pentamidine as prophylaxis (by reading notice in the Federal Register), a similar request is filed by Lyphomed.

1988 Lyphomed receives orphan drug status.

1989 Lyphomed regimen approved by FDA on the basis of a single unblinded dose-response study while Fisons is still gathering data from its multicenter double-blind placebo- and low dose-controlled studies required by FDA. Orphan drug exclusivity arguably attaches to the Lyphomed regimen, foreclosing the Fisons regimen from the market until 1996.

SAN ANTONIO METROPOLITAN HEALTH DISTRICT

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March 16, 1990

Ms. Ruth Katz, Staff
Subcommittee on Health and
the Environment
2424 Rayburn House Office Bldg.
Washington, D.C. 20515

Dear Ms. Katz:

Dr. Guerra has asked that I respond to your request for clarification and expansion on his comments before the Subcommittee last week. Specifically, we will address two areas that were brought up in Dr. Guerra's presentation.

Dr. Guerra made the comment that the majority of vaccine preventable disease cases in our community were among indigent residents. We based this observation on our analysis of Pertussis cases in Bexar County in 1989. We did a geographic distribution of cases by census tract and then looked at the 1980 median household income for these tracts.

As you can see from the attached table, out of a total of 40 cases, 26 or 65% were from tracts where the median household income in 1980 ranged from 38.9% below poverty to 90.9% above poverty. Seven of the cases, or 16% were in tracts that had household median incomes from 38.9% to 13.6% below poverty levels.

We consider households that have income up to 100% above poverty levels to be medically indigent. Medical indigency means that this household would spend all of its available income on food, shelter, clothes and transportation and depend on the public sector for medical and health care.

In Dr. Guerra's written testimony the following statement was made "In San Antonio we experience all of the normal constraints and impediments to the provision of adequate immunization services that any other large metropolitan city faces". Among the impediments that were implied are those that result from a shrinking base of resources.

We have not been able to keep up with the growth and changing demographics in our community. While absolute dollars for Public Health have remained fairly constant, when adjusted for inflation, we have actually lost ground over the past few years. For example, in 1980 the City General Fund allocated $8.38 per capita for Public Health Services, due to inflation and growth in population in the community this had fallen by 12% to $7.40 in 1987.

In 1980 the local Health Department had 8.8 Registered Nurses per 100,000 population. By 1987 this figure had decreased by 18% to 7.2 per 100,000 population. Demand continues to grow for Public Health services, but resources needed to meet this demand do not grow accordingly. Negative changes in the economy place more demands on a system when fewer resources are available to meet this demand. This would appear to be a universal problem throughout many communities in the country.

Other "impediments" include lack of transportation, clinic hours that are not convenient to working parents, inability to attract and retain high caliber staff in a competitive market for health professionals, and the inability to adequately motivate the public to utilize service systems that exist.

The above represents Dr. Guerra's expansion of his comments before the Subcommittee last week. Please let us know if additional detail or information is required.

Cordially,

J. Scott Highley,
Health Planner

1989 Pertussis Cases by Census Tract
Bexar County, Texas

C.T.:	# Cases:	1980 Median Household Income	% 1980 Income Above or Below Poverty:
1103	5	$4,583	-38.9
1307	1	$6,121	-18.4
1305	1	$6,483	-13.6
1701	1	$7,612	1.5
1703	1	$7,699	2.7
1301	1	$8,104	8.1
1501	1	$8,453	12.7
1304	1	$8,883	18.4
1402	2	$9,401	25.3
1610	1	$9,818	30.9
1403	1	$10,041	33.9
1606	1	$10,817	44.2
1510	1	$12,268	63.6
1611	1	$12,480	66.4
1412	2	$13,894	85.3
1613	2	$14,017	86.9
1615	3	$14,315	90.9
1805	1	$15,612	108.2
1801	3	$16,250	116.7
1909	1	$17,129	128.4
1813	2	$19,763	163.5
1810	1	$20,000	166.7
1719	1	$20,446	172.6
1806	1	$20,862	178.2
1818	2	$21,054	180.7
1817	1	$24,173	222.3
1209	1	$24,956	232.7
Total:	40		

Cases in CT's With Household Income up to 90.9% above poverty level- 26

% of Total 1989 Pertussis Cases 65.0

1980 Bexar County Median Household Income - $15,085

1980 Poverty Level Income for Family of Four - $7,500

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